

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

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IN RE: VALSARTAN PRODUCTS
LIABILITY LITIGATION

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
October 4, 2024
Commencing at 10:30 a.m.

B E F O R E: THOMAS I. VANASKIE (RET.)
SPECIAL MASTER

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1 (PROCEEDINGS held via Teams before SPECIAL MASTER
2 THOMAS I. VANASKIE at 10:30 a.m.)

3 SPECIAL MASTER VANASKIE: I thought we would start
4 with the matters that were raised in David's email that
5 identified the specific pages of the testimony and exhibits on
6 which I had reserved ruling.

7 And I thought we could go there first.

8 Give me a second to pull that back up. Too many
9 things going on.

10 We're going to start with Nassall's testimony at
11 page 97. And perhaps we should start by having you, Victoria,
12 state again your arguments for seeking to exclude this
13 testimony.

14 MS. LOCKARD: Okay. So this is the issue involving
15 communications related to the 2011 audit, which we maintain is
16 not relevant to the case at hand.

17 SPECIAL MASTER VANASKIE: Okay.

18 MS. LOCKARD: And it was the issue of whether
19 plaintiffs were sufficiently able to connect the dots
20 considering Judge Bumb's ruling about issues having to be
21 connected directly to valsartan and the issues in this case or
22 proving a systemic issue that is probative.

23 SPECIAL MASTER VANASKIE: All right. Thank you for
24 refreshing my recollection at least on this particular point.

25 David, how do you connect the dots?

1 MR. STANOCH: Thank you, Your Honor.

2 First of all, I'd like to remind Your Honor that this
3 exact same audit came up with a prior witness last week, I
4 believe Mr. Vadsola. And Ms. Lockard made the exact same
5 argument and we had the exact same argument with Your Honor.
6 And Your Honor overruled her objections as to the 2011 audit.

7 And you said in the 9/26 transcript at page 24,
8 starting at line 14: Yes, I -- my initial inclination was to
9 allow this. I believe my initial inclination was correct. I
10 think it is sufficiently tied. The dots are sufficiently
11 connected to allow this testimony to come in.

12 We already have a ruling, Your Honor, on the
13 relevance of this audit, number one. So I think -- and
14 Ms. Lockard has not presented anything that would change the
15 arguments and ruling from the other week.

16 And then I don't want to go too much into it again,
17 because we've already argued it last week, but again, this
18 relates to valsartan being made at the exact ZHP facility
19 about a systemic issue, an issue with ZHP's change controls
20 for valsartan API, which we will see time and time again,
21 other evidence has shown to Your Honor and we'll show at
22 trial, that there were change control issues at ZHP and that
23 the change control issue, as to valsartan and overall their
24 CGMP compliance with proper change control, is what led to the
25 issues regarding the TEA to zinc chloride process.

1 And I believe Ms. Lockard even conceded that systemic
2 issues are relevant in what she had just said to Your Honor.

3 And clearly our story is Teva lacks oversight from a
4 quality perspective of ZHP. And this goes to that very issue.
5 It falls -- it's relevant. It satisfies Judge Bumb's
6 ruling -- which I might add, was not some fiat across all
7 things. It was about a specific Torrent document.

8 I'll stop there.

9 SPECIAL MASTER VANASKIE: All right. Thank you.
10 Victoria, your rebuttal?

11 MS. LOCKARD: Yes, Judge.

12 I understand that you, Judge, made an initial ruling
13 on this with a prior witness. And that's why we submitted the
14 motion in limine transcript, so that you could have the
15 benefit of what had been discussed previously with Judge Bumb.

16 And, respectfully, we feel like any testimony
17 regarding the 2011 audit should be out.

18 So, you know, now that you've had the benefit of
19 Judge Bumb's comments on this, I think that provides some
20 light on what her thinking was and her concern about all of
21 these issues pervading the trial and creating various mini
22 trials. That is a very real concern, particularly under the
23 time limits that we've been given.

24 This issue, just because it relates to change
25 control, does not make it systemic. Systemic means something

1 that is impacting and affecting the entire system.

2 Having just one reference in a 2011 audit related to
3 a change control, not related to the change that led to the
4 nitrosamine issue, that does not make it systemic and it
5 doesn't make it relevant.

6 And so, you know, our position is that you can't just
7 say, well, they had a CGMP violation that related to a change
8 control, therefore, it's a systemic problem at ZHP altogether
9 and we should have known about it.

10 Keeping in mind that that facility itself is not
11 where Teva's API was made. It's not where Teva's ZHP API was
12 made. And if there are issues with that facility, we think
13 that should be addressed with ZHP, not with our witnesses.

14 MR. STANOCH: Your Honor, I'm happy to respond.

15 SPECIAL MASTER VANASKIE: Yeah, please do.

16 MR. STANOCH: Thank you, Your Honor.

17 Number one, that's incorrect, that Chuannan is the
18 only ZHP API facility, period. This is an audit of that
19 facility.

20 MS. LOCKARD: I misstated on that. I'm sorry.
21 You're correct.

22 MR. STANOCH: Thank you.

23 MS. LOCKARD: This is not the Zhengzhou facility,
24 this is the one at Chuannan. But my relevance argument is
25 still valid.

1 MR. STANOCH: May I proceed, Your Honor?

2 SPECIAL MASTER VANASKIE: You may proceed.

3 MR. STANOCH: Thank you.

4 The change control issues at ZHP's Chuannan
5 facility -- this facility that Teva was auditing and found
6 issues with about inadequate change controls in 2011 is at the
7 heart of this case.

8 The FDA --

9 SPECIAL MASTER VANASKIE: Connect it up to the
10 contamination and the valsartan contamination.

11 MR. STANOCH: The FDA's warning letter to ZHP
12 specifically cited ZHP's failures to have change --
13 appropriate change control policies and procedures.

14 SPECIAL MASTER VANASKIE: Now, tie that in, please,
15 to the contamination at issue here.

16 MR. STANOCH: Yes. And that because ZHP had
17 ineffective change control procedures when it instituted
18 changes on how it made the API, it did not properly assess the
19 API for impurities. When they changed the formula, right --
20 this is -- and by the way, this audit is right around the same
21 time. The formula change is happening 2011-2012.

22 SPECIAL MASTER VANASKIE: Right.

23 MR. STANOCH: So this is all happening almost
24 contemporaneously.

25 For example, ZHP was faulted as part of their

1 insufficient change controls that they did not undertake a
2 proper analysis when they scaled up from test batches to full
3 commercialization, that they weren't following proper
4 procedures in terms of what they should be looking for and
5 analyzing and testing for impurities with the API. Right?

6 SPECIAL MASTER VANASKIE: What liability theory is
7 this tied to?

8 MR. STANOCH: It's tied to our liability theory
9 against both Teva and ZHP. Our theories of liability is
10 obviously the drugs were adulterated, but also that they were
11 made -- they were adulterated not just for contamination, but
12 because they were made in a non-CGMP compliant manner. And
13 that's what the FDA ultimately said in their root cause
14 analysis of this very facility about ZHP's ineffective change
15 controls.

16 And our theory of liability in part is Teva, as the
17 seller of the finished dose, had non-delegable obligations
18 under CGMP to exercise appropriate quality oversight of their
19 supplier, ZHP.

20 This goes to the fact that they did not do that
21 because they identified an issue, an issue which these
22 documents show was an urgent -- their words, not mine -- an
23 urgent for-cause audit concerning failures of CGMP regarding
24 to change controls for valsartan.

25 And they did nothing. And in fact, they continued to

1 buy from them. And in fact --

2 SPECIAL MASTER VANASKIE: All right. I think I
3 understand your argument.

4 Victoria, any response?

5 MS. LOCKARD: Your Honor, this is the same rationale
6 plaintiffs gave Judge Bumb when they were arguing about the
7 Meridan or Meridian report.

8 The Meridan report Judge Bumb excluded and that
9 capped off this whole discussion.

10 The Meridan report, the reason plaintiffs said that
11 was so relevant was because it related to testing and
12 validation, which are the other issues, just like change
13 control process, that they say are core, central to the case
14 involving nitrosamines.

15 And that's -- you know, they said it's the same
16 issue. It's testing and validation. And the Court said it
17 doesn't matter. It's one event, an isolated event. It's not
18 systemic, and it doesn't come in.

19 So just because you have a single, sole observation
20 from one report that has an observation similar to what
21 plaintiffs are claiming in the nitrosamine issue, that does
22 not connect the dots, just like with the Meridan report.

23 You can't just say, okay, they did the same CGMP
24 violation as they did for nitrosamines. If that were the
25 standard, then the Meridan report would have come in.

1 So it has to be more than that. It has to be
2 something related to the nitrosamine causation of why it ended
3 up in the drug, but it also -- it has to be systemic. It
4 can't be this, you know, one time -- you know, one
5 observation, one-product event.

6 So I think that's all I really need to say about
7 that.

8 SPECIAL MASTER VANASKIE: All right. David, briefly,
9 please.

10 MR. STANOCH: Thank you, Judge. I'll be brief. I'll
11 be very, very, very, very brief.

12 We're going so far afield now with the Meridan
13 report. That was a third-party report, number one. This is
14 Teva's own internal auditor, right, doing an urgent audit
15 about change controls, number one.

16 Number two, the Meridan report dealt with other
17 products, not valsartan. This specifically is about valsartan
18 change controls at the exact ZHP facility.

19 Number three, this is much more temporally relevant
20 than the Meridan report, which was done not only about other
21 products, but at a later time. This is right smack in the
22 middle of when ZHP is implementing the change control to
23 change the recipe or formula for valsartan in 2011 and '12.

24 And finally, just one more thing, Your Honor, they
25 are going -- Teva is going to argue that they did everything

1 right, they were CGMP compliant, they never had a reason to
2 think there was a CGMP problem at ZHP about valsartan.

3 And we're allowed to rebut that. And this is an
4 example of that. And Ms. Lockard threw in I think mini trial
5 or time limits. That's not what she started with. She
6 pivoted to that. And we always hear her say "mini trial," I
7 strongly disagree with that. We're talking about literally a
8 couple minutes of testimony here, both experts on both sides
9 look at all of these audits from 2011 to 2018.

10 We say this should have tipped off Teva that there
11 was an issue regarding change controls and they should have
12 asked further questions. Their expert says, no, we don't.
13 That's it. There's no mini trial here.

14 I think that's an inappropriate and not well-founded
15 objection.

16 SPECIAL MASTER VANASKIE: All right. Thank you.

17 Well, I'm going to return to the ruling I made back
18 on September 26th. I understand that Judge Bumb has made a
19 ruling, but it doesn't alter the fact that I think the
20 plaintiffs have shown that this audit and the observations
21 made in connection with it are sufficiently tied to the
22 liability theories being presented in this case.

23 This exhibit should be considered along with the
24 testimony, and so I will allow the testimony -- I lose track
25 of pages.

1 MR. STANOCH: I believe it was 97, line 9 to page 99,
2 line 4, Your Honor.

3 SPECIAL MASTER VANASKIE: And that testimony will
4 come in.

5 MR. STANOCH: Thank you, Judge.

6 MS. LOCKARD: Yes, Your Honor. And I understand
7 that. And I'm not going to belabor this, but I did just want
8 to make my point for the record.

9 So this argument that we have with relation to
10 failure to connect the dots, it goes to both the 2011 audit of
11 the Chuannan facility and there was a 2016 audit -- 2015-2016,
12 in that time period, of the Zhengzhou facility, which is why I
13 mixed those two up a few moments ago.

14 But we had an argument -- similar argument as to
15 that. We had a similar argument as to the 2019 audit.

16 So just for purposes of clarification on the record,
17 there may be additional testimony that comes up with other
18 witnesses that we object to based on same argument, but as to
19 the other audits.

20 SPECIAL MASTER VANASKIE: All right. I'd have to
21 look at those individually. I'm not making a determination
22 outside the confines of the pages of the testimony of
23 Mr. Nassall that have been presented to me.

24 That's at pages 97 to 99, 100 to 101, and 104 to 107.

25 And this deals with Teva exhibits or Exhibit 270 and

1 Exhibit 318.

2 MS. LOCKARD: Understood.

3 MR. STANOCH: Thank you, Judge.

4 SPECIAL MASTER VANASKIE: All right. Now can we
5 proceed to Mr. Karlsson's, the testimony that's at issue with
6 respect to Mr. Karlsson?

7 MR. STANOCH: Yes, Your Honor. And if I may, may I
8 make a suggestion?

9 SPECIAL MASTER VANASKIE: You may make a suggestion.

10 MR. STANOCH: Thank you, Your Honor.

11 In the email we sent to Your Honor last night, we
12 tried, per your request, to group the remaining designations
13 from Karlsson sort of based on subject matter of the
14 testimony. And it fell into about four or five buckets.

15 And we had been talking about routes of synthesis,
16 et cetera yesterday. We could start there and proceed
17 through. Or if Your Honor wants to put a pin in that and
18 address the next two that are at 267 and 274.

19 I think the principal issue there is about literature
20 and articles.

21 SPECIAL MASTER VANASKIE: Let me back up for a second
22 here. I'm sorry to interrupt you, David.

23 MR. STANOCH: Sure. No, no, of course.

24 SPECIAL MASTER VANASKIE: The ruling I just made, I
25 take it covers excerpts of Nassall, Karlsson, and Pan Lin that

1 are mentioned in your email of last night.

2 MR. STANOCH: It would -- I believe, Your Honor, that
3 your ruling would address all of the excerpts for Mr. Nassall
4 of my email of last night.

5 I believe it would include -- well, that was the only
6 one about the audit.

7 SPECIAL MASTER VANASKIE: Okay.

8 MR. STANOCH: I think that's where we need to stop,
9 unfortunately, Judge.

10 SPECIAL MASTER VANASKIE: Yeah. And I think we got
11 off the rails a little bit there.

12 I want to stick to your email.

13 MR. STANOCH: Okay.

14 SPECIAL MASTER VANASKIE: And the testimony on which
15 I had reserved ruling.

16 Then we'll go to Karlsson's testimony.

17 MR. STANOCH: Yes, sir.

18 SPECIAL MASTER VANASKIE: So what I'd like to do
19 is -- give me a second to get it in front of me -- but this
20 would deal with Teva Exhibit 32.

21 MR. STANOCH: Yes, sir.

22 SPECIAL MASTER VANASKIE: And the associated
23 testimony.

24 Let me get your email in front of me.

25 MR. STANOCH: Yes, sir.

1 SPECIAL MASTER VANASKIE: So now we want to go to
2 Mr. Karlsson's testimony, spanning pages 160 to 165, dealing
3 with Teva Exhibit 32.

4 MR. STANOCH: Yes, sir.

5 MS. LOCKARD: I believe, Your Honor, this was in
6 relation to an email where Mr. Karlsson was talking about
7 additional measures that he recommended be implemented after
8 this incident.

9 SPECIAL MASTER VANASKIE: Right. Exactly.

10 MS. LOCKARD: And you had ruled that all of these
11 were out. And I think Mr. Stanoch is challenging that or
12 providing context.

13 SPECIAL MASTER VANASKIE: All right. David?

14 MR. STANOCH: Yes, Your Honor.

15 And I think -- I don't want to belabor it, because I
16 understand your tentative ruling pending this, but the defense
17 tried to shoehorn a 407 subsequent remedial measure about this
18 testimony and the underlying document.

19 And as I mentioned the other day, I'll just reiterate
20 that this isn't some after-the-fact document or discussion.
21 If Your Honor will see, it's all from -- contemporaneous with
22 the notifications in June from ZHP to Teva. And that it's all
23 about -- if you look, it starts from June 21 and it's back and
24 forth about the genotoxic impurity notification for valsartan
25 from ZHP to this -- to Teva.

1 And it goes back and forth about the materials that
2 ZHP is sending to them, and Mr. Karlsson asking for more
3 details about the impurity and the levels that are being
4 detected. And ZHP writes back, here's the NDMA information
5 package and root cause investigation and background of the
6 event. Background of the event. This is talking about what
7 was going on.

8 So I don't think this is of the same type of document
9 that was subject for the one motion in limine ruling about
10 sort of divorced from the events, thoughts of Mr. Karlsson
11 about what Teva can do in the future. This is really part and
12 parcel of the timeline of events of what was happening at the
13 time.

14 MS. LOCKARD: So, Your Honor --

15 SPECIAL MASTER VANASKIE: Go ahead, Victoria.

16 MS. LOCKARD: Yes.

17 So we don't have any objection to a contemporaneous
18 discussion of the events and the factual events of what
19 happened and what notice ZHP provided to Teva. What we have a
20 concern about is that this is the -- these are the R&D people
21 talking about other products in development, talking about
22 looking into this issue and what they need to do and what --
23 how they need to tighten things up as a result of what
24 happened with the nitrosamine issue.

25 So they're recommending additional testing. They're

1 saying, you know, measures that they should be taking now on
2 the development side with respect to ZHP that were not in
3 place before.

4 And it's a direct result of the notification.

5 So of course there's some discussion of the
6 notification and what the factual occurrences were, because
7 that's what gives rise to the recommendations that we do more
8 testing and change things.

9 So the fact that it's intertwined with the actual
10 facts of the events, it doesn't negate the argument that
11 anything discussing what should be changed or what should be
12 done is still a subsequent remedial measure. It's still
13 irrelevant. We don't dispute the factual circumstances. And
14 there's plenty of evidence of that.

15 So this is not needed to get into factual evidence of
16 what happened to bring about this issue.

17 SPECIAL MASTER VANASKIE: David, connect this to the
18 claim that you have in the case.

19 MR. STANOCH: Yes, Your Honor.

20 So this discussion is about what was being done or
21 not done about the API at issue, the valsartan API --

22 SPECIAL MASTER VANASKIE: I understand that. But
23 what claim is it connected to?

24 MR. STANOCH: The -- well, first of all, two things.
25 I'll answer your question directly, but just first I just want

1 to note for this 407 argument, that even assuming what
2 Ms. Lockard says is correct, this also goes to control and ZHP
3 and Teva's control over ZHP and ability to actually oversee
4 and control them in terms of what its supplier, ZHP, does or
5 does not do with respect to the API.

6 So that -- that takes it out of the 407 world,
7 because you can still have -- even if this was subsequent
8 remedial, you can still --

9 SPECIAL MASTER VANASKIE: I understand. You can have
10 another purpose. Go ahead.

11 MR. STANOCH: Yes, sir. Thank you.

12 And then in terms of connecting it, Your Honor, this
13 is showing the back-and-forth between ZHP and Teva and what
14 testing was or was not being done at the time of this actual
15 valsartan API. And this is before anything was recalled.

16 SPECIAL MASTER VANASKIE: All right. Brief rebuttal,
17 Victoria.

18 MS. LOCKARD: Your Honor, it was before the actual
19 recall, but it was after the event. And subsequent remedial
20 measure doesn't say anything about a recall. It says after
21 the events giving rise to the claim.

22 So I don't think the timing argument is persuasive.
23 This is -- this is directly talking about adding a method to
24 test this new impurity. That is adding a new measure
25 subsequent to the event in order to remediate things.

1 It is not relevant to the claim because anything that
2 happened after that event has no probative value on the claim
3 and what was actually being done at that time.

4 Plaintiffs can argue, well, they weren't doing this
5 test method, they didn't have this test method and that was
6 the problem.

7 But then to come in and bring the corporate documents
8 in and say, oh, aha, but there was a witness who acknowledged
9 that they should have been doing this before and they need to
10 start doing it now, that's the definition, the classic
11 definition of a subsequent remedial measure.

12 MR. STANOCH: Two quick points.

13 SPECIAL MASTER VANASKIE: All right. Brief rebuttal.

14 MR. STANOCH: Thank you, Your Honor. Two quick
15 points.

16 Number one, our claim in part is that these products
17 were not CGMP complaint and that the finished dose was not the
18 FDA-approved version as a result of that and it resulted in
19 the breach of warning.

20 This is showing that the product was not properly
21 tested, therefore, it was not CGMP complaint, therefore, it's
22 relevant to our liability claims regarding the breach of
23 warranty about this being represented to be something and it
24 wasn't that thing.

25 And also, I'd also suggest that this also shows

1 feasibility of precautionary measures, which, again, takes it
2 out of 407. They simply could have been doing the right test
3 the whole time, which we say is a CGMP violation anyway. It's
4 not about something, what we should do in the future. It's
5 showing you could have been doing this feasibly the entire
6 time.

7 SPECIAL MASTER VANASKIE: All right. I will overrule
8 the objection, allow this testimony to be presented to the
9 jury, along with the associated exhibit.

10 MS. LOCKARD: Okay. So is that --

11 SPECIAL MASTER VANASKIE: This is Teva 32 and
12 Mr. Karlsson's testimony at pages 160 to 165.

13 MS. LOCKARD: Right. That was going to be my
14 question, just confirming that that relates to all of that
15 testimony.

16 SPECIAL MASTER VANASKIE: It does.

17 MS. LOCKARD: Yep.

18 SPECIAL MASTER VANASKIE: And now we have Pan Lin.

19 I think there's a typographical -- or an error with
20 respect to the page designation --

21 MR. STANOCH: Yes.

22 SPECIAL MASTER VANASKIE: -- or the page and line
23 designation --

24 MR. STANOCH: I apologize --

25 SPECIAL MASTER VANASKIE: -- for Pan Lin.

1 MR. STANOCH: -- Your Honor. That was my fault.

2 That should be 230, page 230, line 7 to 23. Not 270.

3 I apologize.

4 SPECIAL MASTER VANASKIE: Yeah. All right. And I've
5 taken a look at this.

6 Let me pull it back in front of me. And it deals
7 with Teva Exhibit 285.

8 MR. STANOCH: Yes, sir. And I'm happy to briefly
9 address it when you're ready.

10 MS. LOCKARD: Was this day 2, David?

11 SPECIAL MASTER VANASKIE: Yeah, it was day 2.

12 MR. STANOCH: Yes.

13 MS. LOCKARD: Okay. Let me get it pulled up.

14 We'll be testing all of our executive function skills
15 here.

16 SPECIAL MASTER VANASKIE: So it's page 230 of his
17 testimony, which is page 92 of the second day of his
18 testimony.

19 MS. LOCKARD: I'm getting there.

20 I apologize. This is --

21 SPECIAL MASTER VANASKIE: I know. Hey, I'm
22 struggling myself.

23 MS. LOCKARD: I'm just... I have to get this
24 technology to work.

25 But it's 230.

1 SPECIAL MASTER VANASKIE: Page 230 of his testimony.

2 MR. STANOCH: Yes.

3 SPECIAL MASTER VANASKIE: Page 92 of the second day
4 of his transcript.

5 MR. STANOCH: Right. The PDF itself, Victoria, it's
6 page 92 of 97 of the PDF, but transcript page number 230.

7 MS. LOCKARD: Right. Okay. Yep.

8 Okay. I'm there.

9 I believe -- so our primary objection to this related
10 to hearsay with respect to the article and it being -- not
11 falling within the exception for learned treatises or
12 literature, which have to be used with an expert and have to
13 be found to be reliable. And those requirements were not met.

14 I do not believe the federal evidence rules allow you
15 to just pull out an article and cross-examine a corporate
16 witness about this. And that is one of the problems that we
17 had with the references to the cancer article that's in here.

18 You know, the other issue was that this is beyond the
19 scope of this witness. This witness is an audit witness and,
20 you know, we're asking him now about cancer literature and
21 about the nitrosamine propensity for causing cancer by -- I
22 mean, referencing the cancer article in and of itself is going
23 to be also subject to Judge Bumb's motion in limine on general
24 cause.

25 But I believe the ruling on this was based on our

1 hearsay argument primarily. I don't have the transcript in
2 front of me from that argument, unfortunately.

3 MR. STANOCH: No. I would agree with that,
4 Ms. Lockard, that Judge Vanaskie indicated hearsay is the
5 basis. And I sought leave for -- limited reconsideration and
6 he granted it.

7 MS. LOCKARD: Yeah. And it --

8 SPECIAL MASTER VANASKIE: On what basis should it
9 come in? I still don't see the basis for allowing this.

10 MR. STANOCH: Yes, Your Honor. And I think the only
11 reason I'm going to revisit this, Your Honor, is because I
12 felt -- perhaps wrongly -- that there's just a little
13 confusion that arose about this testimony and what the actual
14 document is. And now that you have the benefit of Teva 285,
15 Judge, we can all see that, I never asked this witness
16 anything about an article. I never put an article in front of
17 him. I didn't pull something off the internet and put it in
18 front of him.

19 This is a business record email between Mr. Lin, a
20 member of the audit team who did this actual audit in
21 September 2018, and other members of that same audit team.
22 And that email in turn attaches another business record.

23 If you look -- it's the visit report of Huahai. It's
24 the risk assessment of the Teva audit team of ZHP. And in it,
25 we look at the -- we look at the page. And I was simply

1 looking at what that business record had included in it. I
2 never asked him anything about an underlying article. I
3 didn't put another underlying article before him.

4 All I was asking was, based on this Teva business
5 record, written by the auditors and the audit team who did
6 this audit. This is the risk assessment they did. This is
7 what they -- this is what they recorded.

8 MS. LOCKARD: But the questioning was, do you see --
9 do you agree that Mr. Kumar cites literature from 1983, after
10 you just asked him -- you said: Mr. Kumar wrote: It is of
11 note, that according to the literature, N-nitrosodimethylamine
12 is formed by the reaction of dimethylamine a nitrosating
13 agent.

14 So it's hearsay within hearsay. You've got an
15 email -- you're asking this witness about Mr. Kumar's email
16 where he is referencing a report and citing a cancer article.
17 And then you go on to ask him about -- you know, you agree
18 Mr. Kumar cites literature as if that's the basis for the
19 statement.

20 And then, you know, you agree it states -- it says
21 literature in parentheses. And then you give the article --
22 you know, the reference or cite, which is Cancer Res (1983).

23 So it gives the impression that you are
24 cross-examining -- and I believe you are cross-examining this
25 witness in somewhat of a circuitous way, but you're basically

1 leading the jury to believe that this witness agrees with what
2 is written in that article.

3 So I think the references to the article and the
4 questioning about the article and the citations to it is what
5 brings it within the objection of hearsay, and that's what
6 really should be excluded.

7 SPECIAL MASTER VANASKIE: I have the same ruling I
8 had before. I will exclude this testimony at page 230 of Pan
9 Lin's testimony. And the exhibit as well.

10 It seems to me, David, this can come in from some
11 other source, but it's not appropriate cross-examination of
12 this witness. It's certainly not appropriate affirmative
13 evidence that you should be presenting.

14 MR. STANOCH: I understand your ruling, Your Honor.
15 I don't think comes under hearsay, but --

16 SPECIAL MASTER VANASKIE: I mean, it can be
17 appropriate evidence, it's just not through this witness.

18 MR. STANOCH: I understand your ruling, Judge.

19 SPECIAL MASTER VANASKIE: All right.

20 I think that takes care of the matters in which I had
21 reserved ruling.

22 MR. STANOCH: I agree, Judge. Thank you.

23 SPECIAL MASTER VANASKIE: So now we're going to go to
24 Mr. Karlsson's testimony starting at page 261.

25 MS. LOCKARD: Okay, Judge. So this was a

1 continuation of a line of discussion relating to Ms.
2 Fridriksdottir's email is where we left off yesterday.

3 SPECIAL MASTER VANASKIE: Right.

4 MS. LOCKARD: And I believe you had excluded the
5 prior designations related to that. And in this particular
6 designation, we had made similar arguments based on relevance,
7 403, foundation, misleading. We also had an argument related
8 to the GC ruling.

9 SPECIAL MASTER VANASKIE: Right.

10 MS. LOCKARD: And that would relate to the references
11 to carcinogenicity at line 10 there.

12 So one of the things --

13 SPECIAL MASTER VANASKIE: Go ahead.

14 MS. LOCKARD: One of the arguments that I had noted
15 is that counsel is essentially paraphrasing what Ms.
16 Fridriksdottir had written. And it's -- it's really
17 misstating the email. And Pan Lin, in asking her -- in asking
18 Pan Lin about -- excuse me -- I'm sorry. In asking
19 Mr. Karlsson about Ms. Fridriksdottir's comment, counsel asks,
20 you know, isn't she suggesting that it's important that Teva
21 do its own analysis.

22 And, you know, Pan Lin -- or excuse me --
23 Mr. Karlsson is saying, yeah, well, I can see what she's
24 written where she's asked if someone has looked through the
25 routes.

1 It's a paraphrasing of the email.

2 SPECIAL MASTER VANASKIE: Right. David.

3 MR. STANOCH: Your Honor, again, it's -- there's a
4 lot there when Ms. Lockard rattles off a law school list of
5 objections --

6 MS. LOCKARD: I mean, I just -- excuse me -- this
7 is --

8 MR. STANOCH: -- so I don't know where to begin.

9 MS. LOCKARD: -- this is second time -- excuse me.
10 This is the second time that you have accused me of rattling
11 off. I don't appreciate it. And I would ask that you treat
12 me with respect as opposing counsel, particularly in front of
13 the Court.

14 MR. STANOCH: I meant no disrespect, Ms. Lockard.

15 And, Your Honor, I'm certainly just trying to
16 understand which of the eight or so objections I should
17 address first to move this proceeding along.

18 SPECIAL MASTER VANASKIE: Avoid the editorial
19 comments and just make your arguments.

20 MR. STANOCH: Yes, sir.

21 The email, to begin with, is relevant, Your Honor.
22 It's discussing the obligations of a finished dose
23 manufacturer, here Teva, when it's sourcing API from someone
24 such as ZHP. And that's what the questions are about. And
25 those obligations are about, you know, what should a finished

1 dose manufacturer be doing and what were the expectations of
2 certain folks in Teva, both --

3 SPECIAL MASTER VANASKIE: Give me a second to find
4 that email again.

5 What's the exhibit number?

6 MR. STANOCH: Oh. I don't know if we sent it, Your
7 Honor. Let --

8 SPECIAL MASTER VANASKIE: Oh, okay.

9 MR. STANOCH: I can send it to you now if you'd like.

10 SPECIAL MASTER VANASKIE: No. Let's continue the
11 argument.

12 MR. STANOCH: And simply put, Your Honor, in these
13 ensuing questions, I'm using the email from his boss, who's
14 talking about the obligations of a finished dose manufacturer
15 sourcing API from a supplier, about what his personal views
16 are, again, of what the expectation is at Teva and what the
17 obligation should be and what they should be doing.

18 The jury will see the testimony email and they'll
19 draw conclusions for themselves, Your Honor, about was -- what
20 Teva thought it should or should not be doing and whether it
21 was doing that or not.

22 And to say that there's a paraphrase or this or that,
23 they'll have the email in front of them. This is a witness
24 who was on the email, testifying about it. He had no trouble
25 giving answers to the question.

1 So I think it's certainly appropriate for him to talk
2 about things that Teva had done in the past or should have
3 been doing in terms of DMF review and routes of synthesis
4 review, which they obviously were not doing at the time.

5 And, plus, the defendants will have other witnesses
6 who claim that they would have never known or could not have
7 known that NDMA could have formed because they didn't have the
8 information. They didn't have enough insight into the ZHP
9 process. That's part of Teva's and, frankly, Torrent's story.

10 And this is going to that and helping rebut that to
11 say Teva folks internally knew, well, we need a route of
12 synthesis to do that analysis. Right? So it's feasible, it's
13 possible. They knew it should be done and it wasn't done.

14 So for them to say we couldn't look at the route of
15 synthesis more, this is saying, no, they knew it's important
16 to look at the route of synthesis, but they failed to do so in
17 this instance with ZHP.

18 MS. LOCKARD: But you excluded all of the prior
19 testimony about this email. And part of the reason that it's
20 not relevant and prejudicial is because this is somebody in
21 the R&D department discussing with Mr. Karlsson these
22 questions.

23 And Mr. Karlsson doesn't know. He says in the
24 answer, I don't know. He doesn't know one way or the other
25 whether anyone at Teva looked at the routes of synthesis for

1 valsartan and other sartans for the possibility of
2 carcinogenic impurities. He doesn't know because he's in the
3 R&D department.

4 And, yes, he's being diligent and he's prodding, he's
5 asking questions because he uses ZHP API in his development
6 products. But he doesn't know about whether Teva looked at
7 the route of synthesis for this. He's not in that department
8 and he's not in the quality department.

9 And so part of it is the context of this entire
10 discussion is the reason that you excluded it, at least those
11 were some of the arguments that I made.

12 And so it doesn't make sense, now we've got this
13 discussion, which flows from an email where everything else
14 has been -- everything else has been excluded. I mean, I
15 guess if he wants to say, you know -- ask the question at
16 line 8 to 14, do you know whether anyone at Teva ultimately
17 looked at the routes of synthesis, and he says, I don't know,
18 I guess I could withdraw the objection to that, 8 to 14, if
19 it's not tied to the email. And, you know, we'll have our
20 quality people address it.

21 Maybe that's a solution to not get so bogged down on
22 this one instance where everything else has been excluded.

23 SPECIAL MASTER VANASKIE: What page are you on there,
24 Victoria? The lines 8 to 14.

25 MS. LOCKARD: I'm on 260. I realize -- well, 260 --

1 it looks like you ruled on that.

2 So I'm just arguing on one that you already ruled on,
3 I suppose.

4 SPECIAL MASTER VANASKIE: Well, here's what's at
5 issue here, page 261, line 6 to 264, line 8.

6 And my ruling is that this should be excluded.
7 Really, the witness provides nothing substantive. You ask a
8 question, David, that I think is objectionable, that is at
9 line 6 of page 262: Do you think it's appropriate for Teva to
10 look through the sartan routes of synthesis itself to
11 determine whether a carcinogenic impurity may arise?

12 And the witness answered: I can't comment on that.
13 Obviously, again, that in-depth review would be done by other
14 functions within the company.

15 It seems to me, again, he's not the appropriate
16 witness on this particular point. And I think for that
17 reason, the inquiry is not relevant. You're not asking a
18 person with appropriate knowledge these questions. And to get
19 an "I don't know" answer from a person without appropriate
20 knowledge I think is inappropriate.

21 So I'll sustain the objections on page 261, line 6 to
22 page 264, line 8.

23 That takes us now to page 267, line 6.

24 MR. STANOCH: I understand your rulings, Your Honor.

25 I just want to state on the record to preserve, if

1 that's okay.

2 SPECIAL MASTER VANASKIE: Sure.

3 MR. STANOCH: Two things. One is, this goes to
4 feasibility. Right? In terms of what should have been being
5 done and if it could have been done and it wasn't being done.
6 And we'll show that he says, oh, quality should be doing it.
7 That's right, they didn't.

8 Number two, Ms. Fridriksdottir, she -- you will
9 recall from yesterday -- global R&D head tasked Mr. Karlsson
10 to look into the routes of synthesis for valsartan API. So it
11 wasn't -- I'm not asking a stranger about something. He was
12 specifically asked by the global head of R&D to do this
13 because of his experience with this product.

14 But I understand your ruling.

15 SPECIAL MASTER VANASKIE: All right. Thank you.

16 Let's go to page 267, line 6 to 274, line 8.

17 MS. LOCKARD: So this is an email from -- and my
18 pronunciation of these names is not as good as Mr. Stanoch's.

19 SPECIAL MASTER VANASKIE: Don't even try.

20 MS. LOCKARD: Agnes, we'll call her, Kristjansdottir
21 And so this line of questioning relates to those.

22 Again, this is an R&D team discussion regarding the
23 European processes. There's no foundation for what this
24 relates to. And this is an email essentially discussing -- I
25 know you don't have it in front of you -- between Agnes and

1 another witness, Alexander Andreev.

2 And Mr. Andreev is sending Agnes a question in an
3 email and he says there's a general query about genotoxic
4 impurities in API. And he's saying, you know, I'm reviewing a
5 DMF in the development, European R&D development department,
6 where there's a statement that there's no genotoxic impurity
7 in the API.

8 And so Agnes responds, and she -- the testimony sort
9 of goes through what her response is. But she also identifies
10 tools that she says she uses when she's faced with a question
11 about genotoxic impurities.

12 So one of it is she references an article, which is
13 the Muller article, and she references an online tool, which
14 is called -- it's Chem Informatics. And she basically says,
15 you know, here are the two tools I use.

16 Well, in this questioning, Mr. Stanoch pulls out the
17 Muller article and starts questioning Mr. Karlsson on it.
18 And, again, we have a hearsay objection based on any
19 questioning related to this Muller argument for the same
20 reasons that we just went through with Pan Lin. We don't
21 think this is the appropriate witness, a procurement person in
22 R&D, to be questioned about the scientific article. We don't
23 think that's admissible.

24 So as to the Muller article, we have a hearsay
25 objection.

1 As to the questioning on the email itself, we have a
2 relevance and a prejudice objection, because we don't think
3 this is relevant. The time period for this -- these emails
4 was back in 2014. It has nothing to do with the nitrosamine
5 impurity.

6 SPECIAL MASTER VANASKIE: Right.

7 MS. LOCKARD: So that's the gist of our argument for
8 this whole line.

9 SPECIAL MASTER VANASKIE: All right. Mr. Stanoch,
10 David?

11 MR. STANOCH: Thank you, Your Honor.

12 The beginning designations of this testimony, Your
13 Honor, is laying the foundation for the subsequent questions.
14 It's simply establishing -- this email that Mr. Karlsson
15 received. Right? He received it. Who were the other people
16 on it? What did they do? They're testing -- they're testing
17 APIs, right, because API is tested by the company for many
18 purposes. Right?

19 So that's up to the point of the questioning of the
20 article. I think it's very appropriate to ask a percipient
21 witness those foundational questions.

22 Number two, the questions about the article are
23 certainly relevant for a number of reasons, a number of
24 non-hearsay reasons.

25 They go to the feasibility of determining whether a

1 product has a genotoxic impurity. It talks about the
2 feasibility at the time of the change that happened here, Your
3 Honor, that this -- this email from -- was it 2014 --

4 SPECIAL MASTER VANASKIE: 2014.

5 MR. STANOCH: -- makes it extremely relevant. All
6 right. This is years before the recall. And she's saying
7 that we can't take an API -- she's saying we can't take a
8 API's word for it that their product is free of genotoxins.
9 Right? There's at least three non-hearsay purposes, Your
10 Honor, for that, if we're going to get to the hearsay
11 objection, if we cut to it. Right?

12 Number one, it's establishing prior knowledge. This
13 is Teva's people who look at DMFs, they say they look at DMFs,
14 which I might add is a relevant point separately, because
15 defendants say we can't look at the DMFs. But regardless, it
16 establishes Teva's prior knowledge. Right? That they knew,
17 as least as of the date of this email, right, and attached
18 article, right, about the information -- about genotoxins and
19 what should or should not be looked for.

20 It's not offered for the truth of the matter
21 asserted. Right? It's merely showing that Teva was on
22 notice, right, of a potential danger, in fact the exact
23 danger -- a genotoxic impurity -- that is at issue in this
24 case.

25 It's publicly available information that's not

1 hearsay because it's relevant to show the information was
2 scientifically discoverable. I'd also add that I think that
3 the article in this part, this instance, is an adopted
4 business record.

5 We have someone who looks at DMFs and API that
6 Actavis is buying. And at the time, this is -- Actavis was
7 also buying API from ZHP for the product at issue. And she's
8 saying, here is the tool I use.

9 I didn't pull this article off the internet and just
10 start questioning Mr. Karlsson. This is something that Teva
11 personnel have adopted as their own record and what they do
12 when they're evaluating genotoxic impurities in API.

13 And, Your Honor, I'm sorry, if I may.

14 I'd also add that I believe Your Honor, with respect
15 to literature cited by a party or a defendant, I believe you
16 had already ruled that literature is allowable. I believe you
17 allowed that with a ZHP witness in the 9/20/24 transcripts at
18 page 46, line 9 to 49.

19 And I think -- I believe it was Ms. Rose earlier this
20 week, on September 30th, reiterated that ruling and their
21 disagreement, but noted at page 35, lines 8 of 16, that Your
22 Honor had allowed and let in literature that was used in a
23 similar manner from the business files of ZHP in their
24 designations.

25 So I would submit that this is the same situation as

1 Your Honor encountered with those ZHP witnesses and
2 literature.

3 MS. LOCKARD: So, Your Honor, first of all, I don't
4 have an objection to the foundational questions, you know, in
5 and of themselves. So that's one thing.

6 The second is, for clarity, Mr. Stanoch made a
7 comment about -- that we say we can't see -- Teva doesn't see
8 the DMFs. We've never said that. There's been a discussion
9 about a portion of the DMF being open, which we have ready
10 access to, and a portion of it being closed. And there's a
11 dispute about whether Teva would have access to the closed
12 portion.

13 So it's not relevant to whether we can see the DMF.

14 But in terms of the hearsay argument, this is not a
15 witness who said that he uses this article as a tool. This is
16 not a witness who is saying, yeah, this is something I know,
17 something I rely on, something that is reliable.

18 If he had said that, you know, plaintiffs would have
19 a better argument.

20 I still think that the rule requires literature to be
21 discussed with the experts. And this article, I'm certain,
22 will be discussed by plaintiffs' experts.

23 So it's not that we're asking to exclude the article
24 itself from trial, but this R&D witness is not the appropriate
25 person to be asked about this article.

1 The fact that it is attached to an email, you know,
2 kept on the company's servers, does not make it a business
3 record that comes in for these purposes. It has not met the
4 requirements to qualify as an exception to the hearsay rule
5 under the learned treatise and literature.

6 And the reason is, for one thing, you know, this
7 witness is -- it's not within his scope to be asking questions
8 about this on a scientific manner or scientific questions that
9 they want to use this for.

10 I mean, they're not using this in the way that they
11 say, to say, well, this is a tool that the company uses and
12 has adopted.

13 It is one witness who has said -- Agnes -- you know,
14 oh, hey, this is a tool that I use. But it doesn't mean that
15 it's reliable or that this witness has indicated -- provided
16 any indicia of reliability.

17 So unlike other rulings which may have been more
18 closely anchored to the witness who's discussing it, this R&D
19 witness certainly has no business talking about a piece of
20 literature that plaintiffs' own experts will be able to cover
21 ad nauseam.

22 SPECIAL MASTER VANASKIE: All right. Mr. Stanoch,
23 David.

24 MR. STANOCH: I will be very brief, Your Honor.

25 Again, non-hearsay purpose. It's offered to

1 demonstrate Teva's knowledge and existence of same.

2 Teva's trying to exclude the fact -- they cannot
3 exclude the fact that they knew about such tools exist and
4 they did know that.

5 I'm not trying to prove the truth of the matter
6 asserted and prove the article's contents. But they were on
7 notice and had knowledge at least by 2014 about this
8 information.

9 SPECIAL MASTER VANASKIE: Give me a second.

10 MS. LOCKARD: I'm sorry, I didn't hear that, Judge.

11 SPECIAL MASTER VANASKIE: I just want to look at the
12 testimony one more time.

13 MS. LOCKARD: Got it.

14 SPECIAL MASTER VANASKIE: My problem, David, with the
15 testimony as it's presented is this witness really doesn't
16 know anything.

17 MR. STANOCH: He has knowledge of the existence of
18 the information and that the Teva company was on notice. And
19 I know Ms. -- the fact that Mr. Karlsson is in R&D, he has
20 testified earlier -- and we have designations already -- that
21 part of his review of API to get purchased, right, is review
22 of the DMF. This is not something that's alien to him. This
23 is part of his job. He's not just a guy who pays money to get
24 API. He's doing technical scientific analysis of the API.

25 SPECIAL MASTER VANASKIE: Maybe Agnes would have been

1 the right witness, but he says at page 272, line 18: Again,
2 exactly what tools and what articles she uses for her DMF
3 review is something that I cannot comment on.

4 That's the whole problem I have with this line of
5 inquiry. You're trying to use this witness to bring in the
6 contents of an article. You're trying to shoehorn the article
7 into the business records exception to the hearsay rule, and
8 it's just not fitting.

9 And so I will sustain the objection to the testimony
10 from page 276, line 6 to 274, line 8.

11 I have complete confidence that this information will
12 be before the jury, but this is not the appropriate person to
13 use to bring that information to the jury.

14 Now we're going to move to 274, line 15.

15 MS. LOCKARD: I believe this is the same issue. That
16 line begins: This is the article that she attached in her
17 email to you and others, and he gives the name of the article.
18 And he's asking about authors to the article.

19 And he's saying -- counsel is saying, well, the
20 authors are from, you know, these pharma companies, like
21 Pfizer and GSK and Merck and J&J, Abbott, Astra Zeneca, and
22 actually bolstering the article to say, look at all these
23 great big companies who have signed off on this.

24 The interesting point is that many of these companies
25 actually have their own nitrosamine recalls after ZHP and Teva

1 figured this issue out.

2 So that's the irony of it. But he's bolstering the
3 article by referencing all of these companies, which are, you
4 know, really irrelevant at this point because now the article
5 is ruled out.

6 But there's also discussion that goes on where the
7 witness, unfortunately, introduces the term "big pharma," but
8 I believe that that would be prejudicial to have testimony,
9 about, quote, big pharma and the big pharma companies in this
10 case.

11 So we think that entire designation should come out
12 as well.

13 SPECIAL MASTER VANASKIE: David?

14 MR. STANOCH: Again, Your Honor, this is an article
15 from 2006. He's testifying about his article in his records.
16 This isn't something we found and put before him. It was
17 something in his own files, in his own emails. It goes to
18 notice and knowledge.

19 And I didn't start talking about big pharma. That
20 was his answer. That was based on his personal knowledge
21 of what -- his characterization of his own document in his own
22 files about it.

23 And I think it certainly is relevant for the jury to
24 hear that the custodian of this document and how he views it
25 and views the authorship of it, I think that's -- I don't see

1 how that's -- it's certainly not prejudicial. It's his words.

2 I didn't suggest that. That was his words, not mine.

3 MS. LOCKARD: Well, just because the witness
4 interjects something that is, you know, prejudicial before the
5 jury, it doesn't mean that it should be allowed.

6 So, I mean, as the gatekeeper, I think the Court
7 recognizes that sometimes witnesses accidentally or
8 unintentionally or unknowingly interject things like this.

9 But I will tell you as well, you know, the moment
10 they bring up this article and start pointing to all of,
11 these, quote, big pharma companies, you know, who generated
12 this article with all of this astute advice, you know, we're
13 going to be able to come back and say, well, look, these
14 companies also missed nitrosamines and they had nitrosamine
15 recalls in their products, which is really going to open the
16 door.

17 So I'm certain that if that -- you know, that Judge
18 Bumb is not going to prohibit us from doing that if they
19 really want to get into naming all these companies.

20 MR. STANOCH: Two quick points, Your Honor, if I may.

21 SPECIAL MASTER VANASKIE: Go ahead.

22 MR. STANOCH: Number one, there's parts of this
23 testimony that focuses on what he was aware of and notice and
24 knowledge as of a certain time. I think that's different than
25 some of the more color commentary that sounds like is being

1 the issue here. Potentially the fact that he was -- he says I
2 was aware or I was copied on it and I knew this existed as of
3 whatever date, I think that's relevant for a non-hearsay
4 purpose, that it existed and then he's acknowledging that he
5 knew or was aware of this.

6 And also, in terms of whether companies -- there's no
7 door opening. Defendants have -- will say at trial any number
8 of times, nobody in the industry knew about the -- that this
9 potential, et cetera, for nitrosamine information. Here's a
10 paper from the early 2000s that rebuts that, showing that
11 others in the industry, which this witness acknowledges are
12 major participants in the industry, are saying what you should
13 be looking at more closely and what you should be doing in
14 terms of potential genotoxic impurities, including
15 specifically nitrosamines.

16 MS. LOCKARD: Well, the article itself also discusses
17 that these types of impurities are unlikely to be found in
18 pharmaceuticals.

19 But we can debate about the meaning of the article
20 and its significance with the experts.

21 You know, the next -- and just to get to -- you know,
22 this ties in very closely to the next designation on this
23 point, which is at 276. And Mr. Stanoch is going through this
24 article talking about a listing of group 2 genotoxic compounds
25 and nitrosamines and sort of trying to get into the meat of

1 this article with this witness, who has readily admitted he
2 really doesn't know about this.

3 And plaintiffs are trying to impose this one woman,
4 Agnes, who happens to have this and use it, they're trying to
5 suggest that this is something that was well-known, used, that
6 it was a tool at Teva broadly.

7 And Mr. Karlsson made very clear that, you know,
8 whatever Agnes uses is -- you know, he doesn't know about
9 that.

10 MR. STANOCH: That's for the jury to decide, Your
11 Honor. He said --

12 MS. LOCKARD: Well --

13 MR. STANOCH: Mr. -- I'm sorry, I let you speak,
14 Ms. Lockard, I'd like to speak, if the Judge permits it.

15 SPECIAL MASTER VANASKIE: You may.

16 MR. STANOCH: Thank you, Your Honor.

17 Mr. Karlsson answers clearly that the question is, so
18 at least as of March 18, 2014, there were science personnel at
19 Teva or legacy Actavis who were aware of the genotoxic
20 potential of nitrosamine in pharmaceutical products. Right?

21 And he goes: I can only say that we were aware of
22 this particular paper. Right?

23 And then he goes on that he was made aware of the
24 article's existence March 18, 2014. Right?

25 Yes. I was copied on that. I have -- yes.

1 So the fact -- they can argue the importance of
2 this -- they're trying to minimize that it's maybe one person
3 who used it for her own reason. That's a jury argument,
4 Judge. I should be allowed to tell the jury that folks in
5 Teva, including this witness, who had the document as a
6 percipient witness to the business record, right, was
7 testifying that he was aware of it and others were aware of it
8 in Teva, period.

9 The significance of that information or what the jury
10 infers from the significance of these particular Teva folks,
11 that's a weight issue. I think the fact that there was
12 information known at Teva, which the witness acknowledges that
13 he and others knew, is something that the jury can hear.

14 And, again, it's a non-hearsay purpose of notice and
15 knowledge in 2014. Again, well prior to the recalls.

16 MS. LOCKARD: If we were to stand up and say, no, we
17 have never heard of this article, you know, I think in that
18 case there may be some relevance to this and there may be some
19 non-hearsay reason for introducing it.

20 But as it stands, he's simply trying to cross-examine
21 the witness on the content of the article, which relates to
22 the nitrosamine impurity that's referenced in what he's
23 quoting from the article.

24 And the rule -- the Rule 803, the exception for
25 statements and learned treatises, it says the statement --

1 it's an exception if it's called to the attention of an expert
2 witness. This witness is not an expert witness.

3 And, B, it has to be established as a reliable
4 authority by the expert's admission. And that hasn't been
5 done.

6 So there's no foundation, it's not an expert, it's
7 not a witness who even says he's ever relied on it or uses it.
8 The only thing he says is, somebody sent me an email with this
9 attached. So it's hearsay.

10 SPECIAL MASTER VANASKIE: Go ahead.

11 MR. STANOCH: Thank you, Judge.

12 Defendants made the very similar argument to Your
13 Honor last week about ZHP and literature, and Your Honor
14 rejected that argument in terms of foundation and experts,
15 that an expert can come in and talk about it and lay the
16 foundation, which they will for this as well. We have a
17 number of experts who included it in their reliance materials.
18 And then that would be for the foundation for the playing of
19 this testimony.

20 So I think that's a non-issue, just as it was with
21 this very similar issue with ZHP.

22 SPECIAL MASTER VANASKIE: All right. I do think this
23 comes in for notice purposes, that Teva -- at least this
24 person at Teva received a copy of the article, was aware of
25 the article. Cannot comment on the significance of the

1 article. That's beyond his competence. But I do think it
2 comes in for notice purposes and will allow the testimony at
3 pages 274, line 15 to 279, line 4.

4 Now I think we can go to 286, line 12 to 19.

5 MS. LOCKARD: So let me just ask you a question, Your
6 Honor.

7 SPECIAL MASTER VANASKIE: Sure.

8 MS. LOCKARD: Because we did have a separate
9 standalone objection to the questions within this designation
10 about the big pharma companies and reference to the companies,
11 who authored it.

12 And my point that counsel is trying to bolster the
13 argument by naming off -- or some might say rattling off -- a
14 number of companies that were the authors. And so even if the
15 question and answer comes in about just to prove -- simply to
16 prove notice, we think the question and answer about, you
17 know, who the authors were and they being big pharmas -- big
18 pharma companies should not come in for separate reasons.

19 SPECIAL MASTER VANASKIE: Under a Rule 403 analysis?

20 MS. LOCKARD: Yes, Your Honor.

21 MR. STANOCH: May I?

22 THE COURT: Go ahead.

23 MR. STANOCH: Very briefly, Your Honor. There is no
24 undue prejudice here.

25 Defendants are all arguing about what the industry

1 knew or did not know about nitrosamines during this very time
2 period.

3 This witness identifies, based on his personal
4 knowledge, all the companies and authors as participants in
5 the industry. That's going directly to rebutting the
6 defendants' argument. It's within his personal knowledge. I
7 don't think the prejudice is undue.

8 In fact, it would be unduly prejudicial for them, for
9 the defendants to be able to continually say the industry
10 didn't know, the industry didn't know, the industry didn't
11 know, and then we can't rebut that with testimony from their
12 own witnesses saying, no, here's an example of what others in
13 the industry knew in fact from 2014, if not earlier.

14 MS. LOCKARD: This is --

15 SPECIAL MASTER VANASKIE: Go ahead, Victoria.

16 MS. LOCKARD: This is the perfect example of what
17 should be covered by the experts.

18 You're now trying to get a European R&D person to
19 confirm plaintiffs' theory that the industry did know about
20 this? This is not that witness. This guy doesn't know what
21 the industry knew. All he can tell you is, I look at the
22 paper and I see these companies I recognize.

23 If the reason for -- if the non-hearsay reason is
24 just simply to prove notice, that Teva got notice, then the
25 designation should be limited to that simple fact: That Teva

1 had this, they had it in their files, it was forwarded per
2 email. Mr. Karlsson had it, he knew it and he had seen it.

3 But all this other extraneous, that should be left
4 out of this testimony for this witness. That should be
5 reserved for the experts.

6 SPECIAL MASTER VANASKIE: I think there's independent
7 significance to the identity of those who signed on to this
8 particular report. It's the witness who identifies the
9 companies as big pharma companies. And I think its relevance
10 is -- the prejudice caused by knowing who signed on to this
11 article, that prejudice is not substantially outweighed by its
12 probative value, and we'll allow this to come in.

13 MS. LOCKARD: All right.

14 SPECIAL MASTER VANASKIE: I think that takes us to
15 286, lines 12 to 19.

16 LAW CLERK: Excuse me, Judge, for just a second.
17 This is Loretta.

18 SPECIAL MASTER VANASKIE: Yes.

19 LAW CLERK: You had said that the testimony comes in
20 to page 279:4, but the objection was to 279:14.

21 I just want to make sure we get that right.

22 SPECIAL MASTER VANASKIE: The email that I got last
23 night went 279, line 4.

24 LAW CLERK: Sorry.

25 SPECIAL MASTER VANASKIE: No. No. I'm glad

1 you're --

2 LAW CLERK: I'm just looking at the -- sorry.

3 SPECIAL MASTER VANASKIE: Let's look at the rest of
4 it. That could have been a typo.

5 MR. STANOCH: I think it was for all --

6 SPECIAL MASTER VANASKIE: We got it at 10:00 last
7 night.

8 MR. STANOCH: Apologies, Your Honor. Both sides were
9 working diligently to get it to you.

10 SPECIAL MASTER VANASKIE: I know.

11 MR. STANOCH: Thank you -- thank you, Ms. Smith.

12 SPECIAL MASTER VANASKIE: I appreciate that.

13 MR. STANOCH: Thank you, Ms. Smith.

14 Right. Because -- it has to be 14, Your Honor, that
15 was the spreadsheet. Because otherwise it cuts off halfway.

16 SPECIAL MASTER VANASKIE: Cuts off in the middle.

17 Yeah. All right. So to be clear, I'm allowing in
18 the testimony from page 274, line 15 to 279, line 14.

19 Now we can go to 286, line 12.

20 MS. LOCKARD: So, Your Honor, we object to this
21 designation because it --

22 MR. STANOCH: We'll withdraw it.

23 SPECIAL MASTER VANASKIE: All right. Question is
24 withdrawn.

25 MS. LOCKARD: Okay. Thank you.

1 MR. STANOCH: I think that would take us to --

2 SPECIAL MASTER VANASKIE: 291 --

3 MR. STANOCH: Yes, sir.

4 SPECIAL MASTER VANASKIE: -- line 14 to the end.

5 MS. LOCKARD: Okay. Your Honor, I think -- all of
6 these relate to the specific email that Judge Bumb addressed
7 in her motion in limine ruling. This relates to Exhibit 49 of
8 Mr. Karlsson's deposition. And this, even more so than the
9 prior email where we had discussed the subsequent remedial
10 measure, 407 issue, this specifically lists a number of things
11 that Mr. Karlsson is recommending in terms of measures to be
12 taken post the event.

13 This was argued before Judge Bumb on the July 23rd
14 hearing at page 45.

15 And she ruled that these are subsequent remedial
16 measures and that -- she said that part of the email should
17 come out. And by "that part of the email," she means all of
18 Mr. Karlsson's recommendations about the changes that should
19 be made.

20 And I would say -- I don't want to move too fast, but
21 I would say, you know, once you take out the portion that
22 Judge Bumb ruled inadmissible, the remainder of the testimony
23 in these lines really lacks foundation and is misleading and
24 confusing and prejudicial, because there's nothing left to
25 anchor it to the jury -- for the jury to understand what it's

1 about.

2 SPECIAL MASTER VANASKIE: So essentially this is a
3 Rule 407 objection?

4 MS. LOCKARD: Correct.

5 SPECIAL MASTER VANASKIE: David?

6 MR. STANOCH: Thank you, Judge.

7 And we understand Judge Bumb's ruling. And, quite
8 frankly, you know, it was a mixed ruling. Right? And she did
9 indicate that suggestions of what to do in the future should
10 come out but descriptions of existing practices at Teva can
11 come in.

12 And I'll be very frank with Your Honor that the way
13 this email is written and the questioning that occurred about
14 it years ago before that ruling, I think it's very difficult
15 to parse. I think it's almost a line by -- would be a -- sort
16 of a section by section, because he's doing both in this email
17 at the same time.

18 You know, for example, he says, one at number one,
19 the company should have a dedicated team specializing in API
20 matters and DMF review. Right?

21 Okay. Is that a subsequent remedial measure?

22 I'm not sure, honestly.

23 But then in that same paragraph, he then writes:
24 Today the review will be done by the person who compiled the
25 dossier. They might review one to two DMFs a year. Not

1 enough in my opinion. Right?

2 That's describing what the practice was and has been
3 up and until that point.

4 So I'm not disputing what Ms. Lockard says about what
5 Judge Bumb ruled as to this email. Whether or not she had it
6 in front of her when she had the ruling, I'm not sure.

7 But as a practical matter, I think it is a little
8 difficult to parse it. And to be forthright, I'm not sure the
9 best way to go with this with Your Honor. I don't know if we
10 sent it to you -- the email last night or if we should go
11 through the individual questioning.

12 And if you think that hews too closely to 407, it's
13 out; and if it's about then-existing practices, it's in.

14 I wish I had a better suggestion, Judge.

15 MS. LOCKARD: Well, and I --

16 SPECIAL MASTER VANASKIE: I'm looking at the email
17 now.

18 MS. LOCKARD: Yeah, I appreciate the opportunity to
19 sort of work together on this.

20 My issue with some of it, and we do kind of have to
21 parse it out, but, for example, the comment about they might
22 review one to two DMFs per year, not enough in my opinion.
23 He's talking about the research and development team. He's
24 not talking about the procurement team that procures API for
25 commercial purposes in the US.

1 So he's talking about a different team, which is not
2 relevant to what was happening. It's not probative of what
3 the quality team or the procurement team that actually
4 procured the API from ZHP in this case.

5 So he's talking about his team on the R&D side in
6 Europe.

7 So I don't think that has any probative value, just
8 for an example to respond to what Mr. Stanoch said.

9 MR. STANOCH: I don't want to go too much back and
10 forth, Judge.

11 I mean, it specifically says in the beginning it's
12 about DMF deficiencies in US.

13 MS. LOCKARD: Your Honor, you said you do have the
14 email?

15 SPECIAL MASTER VANASKIE: I do.

16 At least the email that's marked as Exhibit 49.

17 MR. STANOCH: That is correct, sir.

18 MS. LOCKARD: That's it. I had it pulled up. I was
19 going to try to share my screen, but no need.

20 SPECIAL MASTER VANASKIE: I want to make sure I'm
21 looking at the correct document, because it's not marked.

22 Let me just get back to your email, David.

23 It's seven pages long. Maybe it's marked as Karlsson
24 Teva 49.

25 MS. LOCKARD: That's right.

1 MR. STANOCH: Yes, sir. Yes, sir.

2 SPECIAL MASTER VANASKIE: So I can see why this 49
3 should not come in.

4 And it seems to me that the questioning that occurs
5 starting at page 291, line 14, you almost have to go question
6 by question.

7 Some of this is -- excuse me, I'm waiting for the
8 fire truck to pass -- post-event remedial measures and some of
9 it's not.

10 So I'm looking at page 299, line 11, the question.

11 Next bullet you wrote was: DMF reviewers should have
12 access to Q-S-A-R, QSAR, software, for example, DEREK to help
13 aid genotox risk assessment.

14 And then the question goes on: What is QSAR
15 software? I'm going to call it QSAR -- Q-S-A-R -- software.

16 That all seems to me to be Rule 407 material.

17 But other questions, have you used QSAR, that's not
18 necessarily a subsequent remedial measure. And you had this
19 at 291 to the end. And the end is where?

20 MR. STANOCH: I meant the end of the spreadsheet,
21 Your Honor. I mean, this email and the questioning about it,
22 I'm pretty sure it would take us through the remainder of
23 Mr. Karlsson's designations.

24 SPECIAL MASTER VANASKIE: That's what I assumed.

25 MR. STANOCH: Yes, sir.

1 Ironically, Your Honor, I was going to suggest that
2 the questioning that you just noted, about DEREK and QSAR, is
3 not a subsequent remedial measure because he's referring to
4 that they are tools and they could be used and that they're
5 not some free online version and that maybe -- you know, I
6 hate negotiating against myself and I'd want a moment to
7 look -- but maybe if we have just that questioning because
8 it's basically saying we're not using QSAR and DEREK -- QSAR,
9 we should, not some free online version. Maybe some of the
10 other questioning before and after that I can withdraw,
11 just to -- in the spirit of compromise.

12 SPECIAL MASTER VANASKIE: Yeah. I think it would be
13 productive if you and Victoria took some time to go through
14 this questioning from 291:14 through the end, wherever that
15 is. Because some of it I think comes in and some of it
16 doesn't.

17 Now, if you want, we can spend the time here and go
18 question by question, but I'd rather you all try to reach
19 agreement.

20 MS. LOCKARD: I think that's a good suggestion. And
21 then there may be a couple of points we can't agree on, we can
22 bring back.

23 But I think that would probably be more efficient.

24 SPECIAL MASTER VANASKIE: Yeah.

25 MS. LOCKARD: And I would suggest for the process

1 that, Mr. Stanoch, that you, you know, go through and reduce
2 the designations to what you think that is not a subsequent
3 remedial measure.

4 MR. STANOCH: That's fair, Ms. Lockard.

5 SPECIAL MASTER VANASKIE: All right. So is that all
6 we can accomplish on this today?

7 Or I shouldn't put it that way.

8 Do you think it's something that could be -- that you
9 could accomplish over the lunch hour?

10 MR. STANOCH: From my perspective, yes.

11 MS. LOCKARD: Sure, sure.

12 SPECIAL MASTER VANASKIE: All right.

13 Do we have any other Teva witnesses?

14 MS. LOCKARD: So, Your Honor, the one witness that
15 Mr. Stanoch has been not so patiently waiting for, I did get
16 to him this morning.

17 I will tell you, I was up late working on this and up
18 early to finish it in time for this, but I recognize
19 Mr. Stanoch did not have time to review it.

20 SPECIAL MASTER VANASKIE: Okay.

21 MS. LOCKARD: And certainly you haven't. So that's
22 my fault and I apologize. But that's where we are.

23 So I don't know that -- I'm willing to go through it
24 today, but I don't know that you or Mr. Stanoch are prepared
25 for that.

1 SPECIAL MASTER VANASKIE: That's Mr. Binsol?

2 MS. LOCKARD: That's Mr. Binsol, yes.

3 SPECIAL MASTER VANASKIE: Okay. All right. Well, my
4 preference would be to give David an opportunity to review
5 your designations and make any counter-designations, get it
6 all at once before I start looking at it.

7 But that's the last witness?

8 MS. LOCKARD: Those --

9 MR. STANOCH: Go ahead.

10 MS. LOCKARD: Subject to -- there are two additional
11 ones plaintiffs have designated, Dr. Nudelman, who is our
12 toxicologist, and he is very much dependent on what Judge Bumb
13 decides with the general cause risk issue because that's most
14 of all what he talks about.

15 And so we're holding off on submitting that one to
16 Your Honor because we think it'll need to be reworked no
17 matter what ruling she comes up with.

18 SPECIAL MASTER VANASKIE: Okay.

19 MS. LOCKARD: The other is Dan Barretto, who is our
20 Teva witness who will be coming to testify live. And we have
21 an issue with -- oh, and I should mention as well, on the
22 general cause issue, we have -- both sides have submitted some
23 letters to Judge Bumb, which we're hoping we can get her
24 viewpoint on that next week, so we should be able to move on
25 to Nudelman hopefully next week or the end of next week.

1 Dan Barretto is a different issue because our
2 position is that he's coming live, and based on the way we
3 interpreted the Court's ruling, we believe that plaintiffs
4 should not be able to play his video in their part of the
5 case, we bring him live and then they get to cross-examine him
6 again.

7 And I know there's been a lot of discussion about
8 that on the record, but I want to get clarification from the
9 Court.

10 I can submit -- I can go through and we can submit
11 his -- our objections to him, but I just don't know that it's
12 worth your time to really address them if the Court sides with
13 us and says, well, you can't play his video. So that's why
14 we're holding off on Barretto.

15 SPECIAL MASTER VANASKIE: David.

16 MR. STANOCH: Thank you, Judge.

17 I agree that Mr. Nudelman, Teva's toxicologist, that
18 most of his designations -- and time-wise there aren't that
19 many. I mean, it's something like 25 minutes or less, so
20 we're not talking a long one -- deal with issues which I guess
21 touch on this general causation issue. I don't know if I'd
22 agree that it does with every single one. But I'm fine if
23 Ms. Lockard wants to wait on that one.

24 Mr. Barretto, we disagree with her position,
25 obviously, that we can't play the video. And in fact, Your

1 Honor spent days going through designations for ZHP and
2 Torrent witnesses, Dr. Jaiswal, Hai Wang and others, who are
3 available and going to be showing up live, I believe, at least
4 in part, that we were able to play designations.

5 But I understand Ms. Lockard's position. I mean, I
6 would be happy to get to you, Your Honor, the Excel
7 spreadsheets and transcripts for both, so you have them and we
8 can hit the ground running at the appropriate time. And just
9 for Your Honor's planning as well, I believe our designations
10 of Mr. Barretto are less than 15 minutes too.

11 So, again, they're -- combined, they're less than I
12 think almost every witness we've dealt with, you know, today,
13 less than Karlsson individually, less than Nassall, less than
14 Pan Lin and Vadsola.

15 SPECIAL MASTER VANASKIE: Well, my suggestion is that
16 you send to me the designations.

17 I know if -- it's not my ruling -- I would allow the
18 excerpts. I would allow the plaintiff to present the case as
19 the plaintiff wants to present it, as long as they were
20 witnesses that qualified as managing agents or officers of the
21 company.

22 If they didn't, it would be -- if they were just
23 regular witnesses, it wouldn't be the case.

24 In other words, if they're persons who can speak on
25 behalf of the corporation, if they were 30(b)(6) witnesses, I

1 would allow the excerpts to be played as the plaintiff wants
2 to play them, even though they're coming in live. I know what
3 that means in terms of the cumbersomeness of the trial, but I
4 think the plaintiff and the defendant are the masters of their
5 cases and can present it as they see fit.

6 But that's not my call to make. But I think if you
7 at least tee it up for me, we can have it ready to go. I
8 won't look at anything until I'm told you've got to look at
9 it.

10 But at least you can get it to me.

11 MS. LOCKARD: Sure.

12 SPECIAL MASTER VANASKIE: So what I'd like to suggest
13 is that you will take an hour-and-a-half for lunch, if that's
14 all right.

15 Ann Marie, you're good for this afternoon?

16 COURT REPORTER: Yes.

17 SPECIAL MASTER VANASKIE: Okay. So we'll resume at
18 1:30.

19 Yes?

20 MS. ROSE: Hi. I'm sorry, Your Honor. I'm not on
21 video. This is Nina Rose for ZHP.

22 I just wanted to clarify something for the record. I
23 think Mr. Stanoch just said that Hai Wang would be appearing
24 at trial, and I just wanted to clarify that he will not.
25 Plaintiffs have stated on the record that they are not calling

1 him live at trial. And he's not. I just wanted to make sure
2 I wasn't on here staying silent when there was an indication
3 that we had done designations for Mr. Wang and he would be
4 appearing at trial. He's not.

5 SPECIAL MASTER VANASKIE: And he's in New Jersey?

6 MS. ROSE: Yes, Your Honor.

7 SPECIAL MASTER VANASKIE: So let's break till 1:30.
8 Try to get me, you know, a pared down -- pare down what needs
9 to be reviewed from 291 to the end of Mr. Karlsson's
10 testimony.

11 Bear in mind, I think some things are clearly
12 subsequent remedial measure and some things aren't. And I
13 will exclude that which is, in my judgment, a subsequent
14 remedial measure, and I will allow that which is not. Because
15 I think his testimony for the most part is relevant, but I'm
16 not prejudging that. It might be there are parts that are
17 either not relevant or the Rule 403 weighing favors Teva. And
18 we'll pick up at 1:30.

19 MS. LOCKARD: Your Honor, could I just clarify for
20 the rest of the agenda today, I don't think Torrent or ZHP
21 have any additional witnesses either, but --

22 SPECIAL MASTER VANASKIE: I did not think there were
23 any other witnesses.

24 MS. LOCKARD: I think it's just -- the only one would
25 be -- I don't know if you're prepared to address it, but there

1 were pharmacy witness designations for two witnesses that were
2 submitted and they're very short.

3 SPECIAL MASTER VANASKIE: And I emailed counsel. I'd
4 hoped you were copied on it. I didn't look; I just replied
5 all.

6 MS. LOCKARD: I probably was. I probably was. I
7 probably just haven't seen it. I've been buried in Tony
8 Binsol's 300-page deposition.

9 SPECIAL MASTER VANASKIE: I said I would take that up
10 at 2:30 today.

11 MS. LOCKARD: I got you. Okay. I apologize for
12 being slow on the email. All right, perfect.

13 SPECIAL MASTER VANASKIE: All right. Anything else
14 before we break?

15 (No response.)

16 SPECIAL MASTER VANASKIE: Thanks, Ann Marie. We'll
17 see you all at 1:30.

18 MR. STANOCH: Thank you, Your Honor.

19 MS. LOCKARD: See you then.

20 (Recess at 12:07 p.m. until 1:37 p.m.)

21 SPECIAL MASTER VANASKIE: So I take it that the first
22 area of dispute is on page 291, line 9 through 293, line 5.

23 Do I have that right?

24 MS. HILTON: Yes, Your Honor.

25 And just for the clarity of the record, Layne Hilton

1 on behalf of the plaintiffs.

2 SPECIAL MASTER VANASKIE: Thank you.

3 MS. LOCKARD: So, Your Honor, if I may, what you'll
4 see, you know, we think plaintiffs have done a reasonable job
5 at cutting down and eliminating many of the subsequent
6 remedial measures uses; however, one of the big issues, I
7 think, just globally on this section is that if their position
8 is they want to use the argument, not to get into what
9 Karlsson was recommending as a subsequent remedial measure,
10 but to show what Teva's practices were at the time, the issue
11 I have with this is that these excerpts don't really do that
12 because Mr. Karlsson doesn't know a lot of what Teva's
13 procurement on the commercial side was doing at the time.

14 And so we have some objections that relate outside of
15 the subsequent remedial measures issue.

16 SPECIAL MASTER VANASKIE: Sure. So that would appear
17 to be the case with respect to the objections on page -- pages
18 291 through 293?

19 MS. HILTON: Your Honor, we included -- if I may,
20 Layne Hilton on behalf of the plaintiffs.

21 We included this portion of the testimony, in part,
22 to try to lay foundation for the subsequent testimony that
23 we're seeking to admit.

24 I mean, this is just sort of background information:
25 Did you send this? Who sent this? Who are these people?

1 This isn't necessarily getting into quite the
2 granular detail that Ms. Lockard, you know, was claiming.

3 MS. LOCKARD: Well, just to address our objections on
4 that section, the designation 291:9 to 293:5, the only parts
5 we're objecting to are lines 18 to 22.

6 SPECIAL MASTER VANASKIE: Okay.

7 MS. LOCKARD: It wasn't originally designated and is
8 superfluous. But if they feel that they need it, I won't say
9 anything more of that.

10 But on the meet and confer, I would be asking
11 Ms. Hilton, do you really need that.

12 MS. HILTON: I mean, I think if we're going to have
13 the before and after testimony, I think it just makes sense to
14 include that one intervening question and answer, and I don't
15 think there's any prejudice to Teva to include it.

16 SPECIAL MASTER VANASKIE: We'll include the exchange
17 on page 291 from lines 18 to 22.

18 MS. LOCKARD: Okay.

19 The next section we object to is 292, lines 16 to 22.

20 SPECIAL MASTER VANASKIE: Right.

21 MS. LOCKARD: And you'll see, this is just
22 introducing confusion, because Mr. Stanoch is asking
23 initially: Well, is that the deficiencies of the team or
24 persons in the US who reviewed the DMFs for Teva?

25 So is this Teva's deficiencies. And he kind of gives

1 an answer non-answer.

2 SPECIAL MASTER VANASKIE: Yes, I found that very
3 confusing.

4 MS. LOCKARD: And the next question we don't object
5 to, which I think gets to the same point.

6 MS. HILTON: Your Honor, I think we would be okay --

7 SPECIAL MASTER VANASKIE: Go ahead, Layne.

8 MS. HILTON: Your Honor, I think we would be okay
9 removing that one discrete question and answer.

10 SPECIAL MASTER VANASKIE: Yes. I think 16 to 22 is
11 out, and then you can go from there.

12 Now, the next one I have --

13 MS. HILTON: Your Honor?

14 SPECIAL MASTER VANASKIE: Yes.

15 MS. HILTON: I was going to say, I apologize, I have
16 been unable to send you the highlighted transcript as I'm
17 having computer errors. So it looks like we're all able to
18 work on it, but I apologize, I cannot -- I have not been able
19 to --

20 SPECIAL MASTER VANASKIE: I can work from the
21 transcript I have in front of me. It's all the same.

22 MS. HILTON: I am having technical difficulties.

23 SPECIAL MASTER VANASKIE: All right. So we're going
24 to go to page 294, lines 8 to 15.

25 I'm confused here. I have also lines 4 to 17.

1 So maybe there's a typo there?

2 Oh, it's my reading that's the problem.

3 294, lines 8 to 15.

4 MS. LOCKARD: Right. We believe both of these are
5 still inadmissible under 407.

6 MS. HILTON: Your Honor, you know, our position on
7 this is that this question and answer is actually just going
8 to the underlying facts. It's not really speaking to any of
9 the subsequent remedial measures. And I think is -- it may be
10 arguably a little bit talking about feasibility but we're
11 just -- you know, this sort of goes to the judge's ruling on
12 the motion in limine.

13 There are some facts in here that I think, you know,
14 would be otherwise admissible if they weren't contained in the
15 email. And I think this question and answer go to those sort
16 of underlying facts, the existence of a team that reviews
17 these measures --

18 SPECIAL MASTER VANASKIE: Yes.

19 MS. HILTON: -- the DMF's.

20 SPECIAL MASTER VANASKIE: I think it does go to a
21 subsequent remedial measure and we'll sustain the objection.

22 MS. LOCKARD: And then similarly on 298 at 4 to 17,
23 this is an excerpt specifically from his excluded email
24 section saying what the company should do.

25 And so, again, we believe this is squarely within

1 Judge Bumb's ruling on subsequent remedial measure.

2 MR. STANOCH: Your Honor, we're good withdrawing that
3 designation.

4 SPECIAL MASTER VANASKIE: All right.

5 MS. LOCKARD: So on the section of 298:18 to 299:10,
6 we object to page 298:18 to 24 because it's 602 and no
7 personal knowledge.

8 SPECIAL MASTER VANASKIE: Layne?

9 MS. HILTON: Your Honor, I think we include it
10 because if they find the remainder of the portion
11 unobjectionable, it sort of gets into the question and answer.
12 Because, you know, the question that begins at 1 is sort of a
13 clarification of what was previously said and might assist the
14 factfinder in understanding the question. But if it's going
15 to be a huge issue, we're okay withdrawing it, but I do think
16 that it helps with the completeness of the designation.

17 SPECIAL MASTER VANASKIE: Well, I'll sustain the
18 objection and just make it clear.

19 So 298, lines 18 to 24 are out.

20 MS. LOCKARD: Okay. So then we go to 299:11 to
21 302:17.

22 And I think we need to really parse this out, which
23 is what I've tried to do.

24 So we object to 299, lines 11 to 18 as being
25 subsequent remedial measure. He's basically saying DMF

1 reviewer should have access to QSAR. And so that objection
2 goes through line 18.

3 SPECIAL MASTER VANASKIE: All right. I will sustain
4 the objection.

5 MS. LOCKARD: And then we're okay with the next
6 question and answer: What is QSAR software?

7 SPECIAL MASTER VANASKIE: That will stay in.

8 MS. LOCKARD: Then he says: Is that a paid or a
9 subscription software?

10 He doesn't know.

11 So that would be objection based on lack of personal
12 knowledge.

13 MS. HILTON: Your Honor, he previously was testifying
14 about it, so I think, you know, follow-up questions about
15 those things, just because he answers I don't know, that
16 doesn't mean lack of personal knowledge; that just seems to be
17 his answer.

18 I think witnesses are clearly entitled to testify "I
19 don't know" and that doesn't mean that retroactively it should
20 somehow be excluded for lack of personal knowledge.

21 MS. LOCKARD: Okay. We'll withdraw that.

22 SPECIAL MASTER VANASKIE: Okay. So that stays in.
23 Now we're up to -- go ahead, Victoria.

24 MS. LOCKARD: So the "have you used QSAR," through
25 line 12, we objected based on no personal knowledge, because

1 he's saying he hasn't been involved in many years and if you
2 want information, you talk to other people, including in
3 toxicology and quality.

4 MS. HILTON: Your Honor, we don't think that this
5 is -- the lack of personal knowledge has merit here.

6 He, obviously -- and we all know sitting here in --
7 you know, in this hearing that he wrote an email about QSAR,
8 DEREK and these sorts of measures. Right?

9 So we know that he does have some knowledge about it.
10 I think the question is permissible. And that his answer
11 indicates maybe he doesn't quite know doesn't mean that it's
12 inadmissible. Because, obviously, through all of the facts
13 and circumstances that we know sitting here today, he does
14 have knowledge to answer questions about QSAR and DEREK. He
15 wrote about it.

16 SPECIAL MASTER VANASKIE: I'll overrule this
17 objection.

18 MS. LOCKARD: Page 300, line 20 to 301:4, we maintain
19 that is a 407 issue.

20 MS. HILTON: Your Honor, I think we'd be okay
21 withdrawing that particular question and answer.

22 SPECIAL MASTER VANASKIE: Okay, great.

23 MS. LOCKARD: And then we object to page 301, line 5
24 to 11 based on 602 and no knowledge.

25 MS. HILTON: Your Honor, I think our argument as to

1 the knowledge pieces is the same as it was for the other
2 questions about QSAR.

3 MS. LOCKARD: So this one I see as a little bit
4 different because before questions were: What is it? Have
5 you used it? Is it free?

6 And this is asking: Well, was Teva using the free
7 online version to do its genotoxic risk assessments?

8 And he does not have any involvement or knowledge in
9 the genotoxic risk assessments.

10 I mean, this is going even more -- drilling down even
11 more beyond just the quality of procurement people, but
12 specifically what is used to perform a genotoxic risk
13 assessment, he -- and then he says specifically he doesn't --
14 I do not know.

15 So that to me is clearly outside of his personal
16 knowledge.

17 MS. HILTON: Your Honor, I would just point out that
18 I think this is permissible cross-examination. And his answer
19 is his answer. And so, you know, I think we're permitted to
20 ask the question in --

21 MS. LOCKARD: Sorry, Layne. He's not a 30(b)(6)
22 witness. If he were a 30(b)(6) witness designated, I would
23 agree, but he's not. He was a witness who was requested by
24 name because of -- you know, his name's in the emails that
25 were produced.

1 So he can't really -- and this is going to be
2 pervasive in some of the remaining testimony. He doesn't have
3 personal knowledge to testify as to what others at Teva on the
4 commercial side in the United States in quality were doing.
5 So...

6 MS. HILTON: I think his answer says, I don't know.
7 And so I think that the answer speaks for itself.

8 MS. LOCKARD: But it's argumentative because it
9 presumes that he should know.

10 SPECIAL MASTER VANASKIE: Yes, I will sustain the
11 objection. So 301:5 to 11 is out.

12 MS. LOCKARD: So 302:7 to 17.

13 SPECIAL MASTER VANASKIE: The notes here say that's
14 okay.

15 MS. LOCKARD: Okay. Yes. We're okay with that.

16 And then the little bit after that were just discrete
17 excerpts of the one before, so I think those are covered.

18 So we go to 303:4 to 305:2.

19 And we have an objection again as to 602 and lack of
20 personal knowledge.

21 And if you read through this section, you can tell --
22 I mean, he says ultimately, I can't comment on that.

23 MS. HILTON: Well, Your Honor, I think our point
24 would be that he authored an email discussing it. He
25 obviously, for the facts of the world, he has personal

1 knowledge to testify about this. I know we're in a different
2 kind of strange scenario at trial, you know, what we
3 previously admitted or not. And I know we're not necessarily
4 admitting that email in full.

5 But I think our view is that he does have personal
6 knowledge, I don't think this question is argumentative, and I
7 think we're permitted to ask it.

8 MS. LOCKARD: Let me just break this down because
9 there is an important distinction here.

10 This question is asking this witness if QSAR and
11 DEREK can identify nitrosamines, not if they can identify
12 potentially genotoxic compounds or impurities. This witness
13 had recommended these programs, generally, for purposes of
14 evaluating genotoxic compounds and impurities. He never said
15 anywhere in his email or in his testimony that these will
16 identify nitrosamines.

17 And that is a big issue in this case. Because
18 plaintiffs are going to say, oh, well, you could have run it
19 through QSAR or DEREK and you would have gotten the answer.
20 And our witnesses are going to say, it doesn't work that way.
21 You can't just program it into a computer, push a button and
22 then it says nitrosamines.

23 So to have him -- this is highly -- I should have put
24 prejudicial. This is highly prejudicial to have this witness,
25 this procurement guy, to come in here and say, oh, yeah, these

1 programs, they can detect nitrosamines, when no quality
2 witness, no testing witness has said that.

3 So that's the distinction. Asking about QSAR/DEREK
4 generally, what is its use, does it look at genotoxic
5 compounds, that's okay; but this is, like, going to almost the
6 ultimate issue of could this have discovered nitrosamines. So
7 we strenuously object to this.

8 MS. HILTON: Your Honor, just briefly, I think
9 Ms. Lockard pointed out why we think this testimony should be
10 in.

11 This is ultimately for the factfinder to make a
12 determination. I don't think it's confusing to them. I think
13 they'll view it in the light of the evidence of the trial.
14 And, you know, I think his answers are his answers and the
15 testimony --

16 SPECIAL MASTER VANASKIE: Again, as I've indicated on
17 prior occasions, I just don't think this is the correct
18 witness to be asking these questions. And I'll sustain the
19 objection.

20 So 303, line 4 to 305, line 2 will not come in.

21 MS. LOCKARD: So moving to 305:3 to 9, we maintain
22 the 407 objection to this as well.

23 MS. HILTON: Your Honor, I think all of the -- if I
24 may.

25 SPECIAL MASTER VANASKIE: Yes, you may.

1 MS. HILTON: If I may, Your Honor, all of the
2 subsequent designations from here on out relate to this
3 question of the questionnaires, which was something that was
4 written in the email.

5 Our position on most of this testimony is that it's
6 not a 407 issue because it goes to the feasibility piece and
7 was it feasible. And I think that's what this testimony is
8 eliciting, whether the questionnaire and the existence of the
9 questionnaire and whether it was feasible to include questions
10 on the questionnaire to determine whether the API suppliers,
11 you know, were manufacturing their drugs in such a way that
12 could result in nitrosamine contamination. I think this is
13 all well within that prong and doesn't even get into the 407
14 analysis.

15 MS. LOCKARD: So let me, if I can, frame this issue.
16 So a number of these -- and we didn't get to talk about this
17 over the break.

18 But a number of these designations go to this notion
19 that Teva is going to stand up at trial and say we could not
20 access the closed portion of the DMF, the DMF, the drug master
21 file, which ZHP keeps.

22 THE COURT: Right.

23 MS. LOCKARD: And there may be other -- there may be
24 other defendants who say that, but this -- plaintiffs, they
25 have an email that was discussed before Judge Bumb where a

1 witness -- I think it's the Gowda email -- where a witness in
2 another connection, in another context, had asked for the
3 closed portion of the DMF. And plaintiffs' argument was, hey,
4 look, Teva can always ask for this. And we fought that. And
5 Judge Bumb excluded that with the proviso that if the door was
6 opened, it comes in.

7 So we are not planning on opening the door. We are
8 not planning on making part of our defense of what we
9 reviewed, what we had access to; we're not planning to stand
10 up and say we could never see the closed portion of the DMF.
11 Because we don't want that email to come in and we don't think
12 it's essential to our case, whether we saw the DMF or not.

13 So there's a lot of questions here that I think are
14 trying to rebut that to say, look, well, Teva says they
15 couldn't see the closed portion of the DMF, but they could
16 always send a questionnaire. Right?

17 So we think this is just going to be irrelevant. I
18 don't think we need to get into this.

19 And it's very concerning to me that now plaintiffs
20 are going to open the door so they can be able to use their
21 own email. And so --

22 MS. HILTON: Your Honor?

23 SPECIAL MASTER VANASKIE: Go ahead, Layne.

24 MS. HILTON: Your Honor, this -- I just want to -- to
25 describe the rest of these designations as only dealing with

1 the DMF is actually totally setting aside the testimony.

2 The questionnaires are about way more than the DMF.
3 The questionnaires are one of the central mechanisms by which
4 finished doses manufacturers like Teva can get information
5 about their API suppliers and is one of the primary ways they
6 exchange this information between the two contracting parties.

7 And so the questionnaire goes into what are your risk
8 mitigation activities. And so I don't think that, you know,
9 to classify all these designations about the open or closed
10 portion of the DMF, that's a very small part of what they're
11 talking about.

12 So I think, you know, our point on this is that even
13 though it was contained in this arguably 407 email, as the
14 judge ruled, we think that information about what they could
15 have asked in their questionnaire and when and was it feasible
16 for them to ask it is well within and, quite frankly, at the
17 heart of the Teva story.

18 MS. LOCKARD: But his specific recommendation in this
19 email is to do a questionnaire. And that was in response to
20 the feeling that we weren't getting sufficient information
21 because the DMF -- DMF was closed.

22 And as you go through these responses, that becomes
23 very evident.

24 MS. HILTON: I think -- I believe, if I'm not
25 mistaken, there were questionnaires that were already in

1 place. I think his recommendation was to add questions.

2 Our point is that this testimony goes to the
3 feasibility of being able to add those questions prior to
4 2028. Or 2020 --

5 MS. LOCKARD: But if you look at lines 14 to 16, you
6 know, the question is about expanding the questionnaire to
7 prevent future valsartan NDMA issues.

8 And he says: Yes, I can see I've written "to prevent
9 future valsartan NDMA issues."

10 So that goes right to the subsequent remedial measure
11 argument.

12 MS. HILTON: I think actually, though, if I'm not
13 mistaken, this email that's been excluded, it attaches a
14 questionnaire that's from 2014.

15 So if we looked at it in the context of the totality
16 of the email, including the fact that there's a 2014
17 questionnaire on there, I don't think it's going to the
18 subsequent remedial measures.

19 MS. LOCKARD: But he says it does in the testimony,
20 which is what you're proposing to play to the jury.

21 MS. HILTON: And our point is that it's not a
22 subsequent remedial measure because it's evidence of
23 feasibility.

24 MS. LOCKARD: Well, I mean, I feel confident in my
25 argument on this as to lines 3 to 16, if we just take that

1 portion. And so I guess the judge -- Judge, if you're ready
2 to rule.

3 SPECIAL MASTER VANASKIE: I didn't know --

4 MS. HILTON: Yes, Your Honor. I'm sorry. The
5 southern ladies went off.

6 SPECIAL MASTER VANASKIE: The more you all talk, the
7 more you work things out.

8 MS. LOCKARD: I don't want to belabor it.

9 SPECIAL MASTER VANASKIE: I just want to see, where
10 are we at? Lines 3 to 16 on what page?

11 MS. LOCKARD: It's line -- 305, line 3 to 16.

12 MS. HILTON: If you see, Your Honor, in that question
13 and answer, there's actually no discussion of what has been
14 happening since 2018. It's about what occurred from 2005 to
15 2012.

16 And we believe that this question and answer is
17 necessary to, you know, sort of at least have a completeness
18 piece for the jury to understand the rest of the testimony
19 that we believe is a subsequent remedial measure.

20 SPECIAL MASTER VANASKIE: I do think this goes to
21 feasibility.

22 I would allow the testimony, the questions and
23 answers on page 305 from lines 3 to 16.

24 MS. LOCKARD: So then we pick up -- wait. I'm sorry,
25 Your Honor.

1 They only designated 3 to 9 on page 305.

2 SPECIAL MASTER VANASKIE: Yes, you're right.

3 MS. LOCKARD: I misspoke. So those are in.

4 MS. HILTON: Your Honor, I think we would be willing
5 to withdraw page -- you know, having heard some of the
6 guidance from the Court, we'd be willing to withdraw page 306,
7 line 9 to 306, line 23, and then maybe even -- or to 24, and
8 starting our designations on page 307:4.

9 SPECIAL MASTER VANASKIE: I'm sorry, can you say that
10 again, Layne?

11 MS. HILTON: So I think we'd -- I'd be willing to
12 withdraw our designations that we have on page 306 and into
13 the top of page 307, and then starting the testimony and the
14 designation on page 307, line 4.

15 MS. LOCKARD: Okay. I'm making a note of that.

16 But I just want to make clear as to page 305, we're
17 not adding anything that plaintiff didn't designate on this
18 chart.

19 SPECIAL MASTER VANASKIE: Correct.

20 MS. LOCKARD: Okay. So looking at page 307, line --

21 SPECIAL MASTER VANASKIE: Page 307, line 4.

22 MS. LOCKARD: This is where we get into the issue of,
23 you know -- and I say here, you know, it's -- we object as to
24 subsequent remedial measures through page 308.

25 But this entire remaining designation, we're

1 objecting as irrelevant, confusing and lacking in personal
2 knowledge based on 602.

3 But if you take this, you know, line by line. So
4 307, question at line 4, this is where they're starting to
5 make the shift --

6 (Interruption.)

7 SPECIAL MASTER VANASKIE: Somebody joined. But go
8 ahead.

9 MS. LOCKARD: This is where we shift to, you know,
10 the dispute about the restricted portions of the DMF.

11 So I think it's confusing because that's not our
12 defense at trial.

13 So this particular witness in research and
14 development, he's adamant that he doesn't have access and his
15 group doesn't have access to the portion of the DMF, the
16 restricted portion.

17 But I think that this is getting into an issue that
18 we agreed we would not bring up at trial for Teva.

19 MS. HILTON: Your Honor, you know, plaintiffs'
20 position on this subject of the questionnaire, again, it
21 goes -- it's not just about the DMF. Right? It's about all
22 of the information that is exchanged between the contracting
23 parties, in this case ZHP and Teva, about their API, about
24 their manufacturing such that, you know, could an entity like
25 Teva have been able to understand and assess the risk and

1 understand that there may have been an issue, and was it
2 feasible for them to have asked more questions that might have
3 alerted them to an issue.

4 And so I think that's -- you know, the word "DMF" may
5 appear in here, but it's about more than that. It's about the
6 exchange of the information.

7 And I think trying to, you know, cut and slice this
8 is going to make it all the more confusing.

9 But I do believe that we are entitled to probe the
10 feasibility of whether Teva was able to ask these questions of
11 its contracting partner prior to 2018.

12 MS. LOCKARD: But we don't dispute the feasibility of
13 that, so it's not at issue.

14 And then if you look at the designations, I mean, at
15 line 17 --

16 (Court reporter clarification.)

17 MS. LOCKARD: So if you look at line 17, the question
18 is specifically asking about the subsequent remedial measure,
19 and in the terms that are prohibited by 407. You know,
20 what -- the question is, what you are suggesting is that, in
21 part, risks could be mitigated. You know, risks such as that
22 that occurred with NDMA could at least be partially mitigated
23 through asking these questions.

24 So, I mean, there's no question about -- if there are
25 questions such as, well, could you have, you know, provided a

1 more expansive questionnaire? Yes. Even a question about,
2 well, should you -- should Teva have done this, you know, if
3 he had personal knowledge, sure.

4 But this is going right to the heart of that email in
5 the suggestion. It even says, what you were suggesting.

6 And so this -- I do think that this line of
7 questioning here, through at least the end of where we're
8 talking about mitigation, which goes all the way through 308,
9 line 18, which --

10 MS. HILTON: Your Honor --

11 MS. LOCKARD: -- is barred by 407.

12 All of this is about his suggestion to mitigate.

13 MS. HILTON: Your Honor, just because --

14 SPECIAL MASTER VANASKIE: Layne.

15 MS. HILTON: Just because -- Your Honor, sorry, I
16 apologize. I'm just overly excited. I've had too much
17 caffeine today.

18 Just because the term "mitigation" is being used in a
19 question, if we think about this testimony and there were no
20 email, say this was just testimony that was being asked at a
21 deposition without an email that just -- you know, whatever it
22 was, Karlsson 47 or 49, whatever the email was, it would be
23 totally permissible.

24 The fact that the word "mitigation" is being used I
25 think is a bit of a red herring. The substance of what's

1 being asked and the substance of how it's being answered goes
2 to what Teva could have done and the feasibility of it. I
3 don't think it gets into improper information from the email.
4 I don't think, you know, we'd even potentially -- I know the
5 judge perhaps allowed us to present this in a redacted form.
6 We might even be amenable to not showing this exhibit to the
7 jury.

8 And I think without that exhibit, there's nothing
9 objectionable about the way that the question was used and the
10 answer.

11 MS. LOCKARD: But the fact is, they didn't. They
12 didn't ask our witnesses. The ones who matter to the quality
13 and procurement team on the commercial side, they didn't ask
14 any of our witness, did -- you know, could you have done an
15 expanded questionnaire. They didn't ask any of them. They
16 asked Mr. Karlsson because they said, what you're suggesting
17 here is, and then here's why.

18 So I would agree if this question had been asked of
19 other witnesses, perhaps, you know, they will get an
20 opportunity with a live witness to ask that. But the sole
21 reason that it's being asked is all framed in, so what you're
22 suggesting, Mr. Karlsson, from his email, is this. And the
23 reason is.

24 So that is exactly what Judge Bumb excluded.

25 MS. HILTON: Your Honor, I'll just say, I do think

1 Mr. Karlsson had personal knowledge. As the procurement
2 person, he is the one that is exchanging the information with
3 the contracting partner. And so we are asking about one of
4 the primary mechanisms that the contracting partners discuss
5 and share information, which is a questionnaire. So I think
6 he's actually probably one of the best people to ask this of.

7 MS. LOCKARD: He's not in the commercial division.
8 He doesn't work on products that are on the market. He works
9 in research and development. And --

10 SPECIAL MASTER VANASKIE: I think I understand the
11 issue. I think I've certainly heard a lot.

12 I think this does go to feasibility. Questions could
13 have been asked. And I would allow the testimony from page
14 306, line 4 through 308, line 14.

15 MS. LOCKARD: I think -- I thought I heard Layne say
16 she was --

17 MS. HILTON: Your Honor, we were willing to get rid
18 of 306:9 to 23, and I think perhaps then starting at 307:4,
19 just to avoid this issue with the open and closed portion of
20 the DMF that Ms. Lockard had argued. So actually --

21 SPECIAL MASTER VANASKIE: I may have misspoken.

22 MS. HILTON: Right.

23 SPECIAL MASTER VANASKIE: So in is 307, line 4
24 through 308, line 14?

25 MS. HILTON: Yes, Your Honor.

1 SPECIAL MASTER VANASKIE: Yes. That's what I meant.

2 MS. HILTON: Yes, Your Honor.

3 MS. LOCKARD: Okay.

4 SPECIAL MASTER VANASKIE: It's a little confusing
5 when I look at the screen, the page numbers are at the bottom.

6 MS. HILTON: I apologize, Your Honor. We were trying
7 to do it very quickly to turn it over, so we didn't
8 necessarily present it to --

9 THE COURT: You guys have done well.

10 Where are we at now?

11 MS. LOCKARD: 309:7 to 309:15.

12 And this, we objected on 407, but I also think this
13 is a little confusing and out of place, because just before
14 this, there were questions where Mr. Karlsson injected the
15 FDA.

16 And Mr. Stanoch said: I'm just asking about Teva,
17 not what the agency has access to.

18 So it's a little bit confusing there and --

19 MS. HILTON: Well, it --

20 MS. LOCKARD: I'm sorry.

21 Additionally, it's cumulative because it's basically
22 saying the same thing that we just agreed would come in.

23 I mean, you get the point that it's feasible, that's
24 been made. He says that was his recommendation and why. And
25 this is just sort of, you know, gilding the lily I guess.

1 SPECIAL MASTER VANASKIE: Layne.

2 MS. HILTON: Your Honor, I think the -- I'll say this
3 is the testimony that we think needs to be admitted. Right?
4 And this goes exactly to what I've been arguing and saying.

5 On page 308, line 5 through 14, you know, the witness
6 testifies, we're trying to get as much information as possible
7 and describing the challenges.

8 Now the question becomes, how do we get a question
9 in, you know, to get that answer introduced?

10 And so we -- I get that there may be some confusion.
11 We'd be amenable to, you know, potentially asking more
12 questions. But, you know, I want to just point out that that
13 line 5 to 14 is, you know, really what we -- I'm sorry, I'm
14 looking at the wrong page. That's on me.

15 SPECIAL MASTER VANASKIE: 5 to 14 is in on page 308.

16 MS. HILTON: That is in.

17 I want to point out --

18 SPECIAL MASTER VANASKIE: We're on page 309.

19 MS. HILTON: Yes. 309:18 to 310:1 is the testimony
20 we're trying to get in.

21 I understand about the confusion of the question, but
22 we need the question in order to have the answer come in.

23 SPECIAL MASTER VANASKIE: I'll sustain the objection.
24 I think you already have this information before the jury in
25 the answer on page 308, lines 5 to 14.

1 MS. HILTON: All right, Your Honor.

2 MS. LOCKARD: So I think that would include --
3 well --

4 MS. HILTON: I think we -- the next one was the
5 bottom of page 310, line 22 to 311, line 17.

6 I think we'd be okay withdrawing our -- you know, for
7 the reasons that Your Honor has previously stated, since we
8 were able to get it in earlier, I understand Your Honor's
9 point.

10 And so we would be agreeable to withdrawing page 310,
11 line 22 to page 311, line 17.

12 SPECIAL MASTER VANASKIE: All right. Very well.

13 MS. LOCKARD: And the next row on the little chart
14 is -- it's contained within what you just withdrew. I think
15 that was just an error.

16 So I think we jump to 313, but let me know if that's
17 not right.

18 MS. HILTON: That's what I have too.

19 SPECIAL MASTER VANASKIE: All right. Let's go to
20 page 313.

21 MS. LOCKARD: So this is asking essentially the same
22 questions. And we objected on 407 and 602 because the
23 question is, you know, asking questions of your supplier is
24 going to go a long way to possibly preventing future NDMA.

25 And the witness finally says: Again, I can't speak

1 to what questions were asked or not asked regarding the
2 valsartan for the US. It's something that I was never
3 involved in, so I can't speak to that. I don't know what
4 questions were raised and what answers were obtained.

5 Now, this is the answer he should have given back six
6 pages ago, but I think this makes pretty clear he doesn't know
7 the answer to this question.

8 SPECIAL MASTER VANASKIE: Layne?

9 MS. HILTON: Your Honor, I mean, I think we argue
10 that it's not 407 because it goes to feasibility, but I
11 understand Ms. Lockard's point here. I think we believe that
12 we're permitted to ask the questions of this witness who
13 obviously wrote an email identifying this particular aspect as
14 something that would go a long way to not having this crisis
15 in the future, and so we believe he does have personal
16 knowledge, at least to the overarching quality systems that
17 would help prevent such a -- from occurring.

18 And so I think that's our position. We do think he
19 has personal knowledge and we think that this testimony goes
20 to the feasibility. And his answers are what his answers are,
21 and the jury is allowed to interpret and give it weight as
22 they would afford any piece of evidence.

23 SPECIAL MASTER VANASKIE: I don't see the need for
24 this. I'll sustain the objection.

25 That would strike the question that appears on page

1 313, starting at line 2, ending with the answer at line 19 of
2 page 313.

3 So I think this takes us now to page 314, line 21.

4 MS. LOCKARD: And we have no objection to lines 21 to
5 23.

6 Then we go to the next row, and we have no
7 objections -- and when I say the next row, I mean the next
8 designation, which is 314:2 to 314:24.

9 SPECIAL MASTER VANASKIE: Okay.

10 MS. LOCKARD: And of that, we have no objection to
11 lines 2 to 12.

12 But as to lines 14 to 24 of page 314, we do object
13 based on 602, no personal knowledge.

14 MS. HILTON: Your Honor, I think the --

15 SPECIAL MASTER VANASKIE: Go ahead.

16 MS. HILTON: I was only going to say, I think, Your
17 Honor, the questions speak for themselves and the answers
18 speak for themselves.

19 I think obviously he has enough personal knowledge to
20 testify on much of these topics, and the jury is permitted to
21 afford the testimony and give it the weight they see fit.

22 SPECIAL MASTER VANASKIE: I'll sustain the objection,
23 because the witness didn't have any personal knowledge.

24 Does that complete Mr. Karlsson?

25 MS. LOCKARD: I believe it does, for plaintiffs'

1 designations and our counters and objections.

2 Again, we are still working to determine if we will
3 have any affirmatives. We may not.

4 We did serve affirmatives for Mr. Karlsson, but they
5 certainly need to be cut down in light of this.

6 SPECIAL MASTER VANASKIE: Okay.

7 MS. LOCKARD: So we'll continue working on that.

8 SPECIAL MASTER VANASKIE: Very well.

9 Layne, anything else on your end?

10 MS. HILTON: Your Honor, I just want to make one
11 brief point about page 314, lines 2 through 12 and the rest
12 that was sustained.

13 You know, I think our position would be he offers up
14 some sua sponte information that his sites were involved and
15 they were asking the right questions. But I think we should
16 be permitted to ask, as a follow-up, that he did have no
17 involvement with valsartan because he's at least trying to
18 extrapolate as though -- you know, that might confuse the
19 jury.

20 MS. LOCKARD: But these questions are suggesting that
21 he should know all of this stuff. And there's no real
22 explanation for -- you know, I had previously proposed that we
23 set this witness up to explain that, you know, he, you know,
24 was working on other projects, but -- I mean, this just
25 suggests that he should be the one to know about this.

1 So I do think that it's going to be misleading and
2 prejudicial if we have a witness just say "I don't know."

3 SPECIAL MASTER VANASKIE: I've sustained the
4 objection. And just to be clear, page 314, lines 14 to 24 is
5 out.

6 MS. HILTON: Thank you, Your Honor.

7 I just wanted to say that for the record.

8 SPECIAL MASTER VANASKIE: No. Say it for the record
9 and make your record. There is no problem with that.

10 MS. HILTON: Oh, no. The record has been made. I
11 just wanted to --

12 SPECIAL MASTER VANASKIE: Yes, it has.

13 MS. LOCKARD: We're all zealous advocates, I can say.

14 SPECIAL MASTER VANASKIE: Yes, yes. That's for
15 certain.

16 MS. HILTON: Thank you, Your Honor, for your time and
17 patience.

18 SPECIAL MASTER VANASKIE: Well, let's see now.

19 Do I have -- I think that concludes Mr. Karlsson.

20 I see, Marlene, you're there?

21 MS. GOLDENBERG: Yes. We're going to swap out a
22 blonde for a ginger now.

23 SPECIAL MASTER VANASKIE: Who do we have on for the
24 retail witnesses? Jacob?

25 MR. RAE: I believe Ms. Kapke is here on behalf of

1 the retailer witnesses, but I think I'm going to be arguing
2 the kind of combined objections of the retailer witnesses and
3 the defendants.

4 SPECIAL MASTER VANASKIE: All right. And is that
5 you, Ms. Kapke, that I see here designated by numbers?

6 MS. KAPKE: Yes, another ginger on the line.

7 I'm counsel for CVS.

8 Kirstin Ives is counsel for Humana. She's also on.
9 So to the extent that there's something about Mr. Cedenro, she
10 can speak to that.

11 I'm here for Mr. Holderman for CVS.

12 MS. IVES: Kirstin Ives on behalf of Humana.

13 SPECIAL MASTER VANASKIE: All right. Thanks,
14 Kirstin.

15 Let me pull up the excerpts and testimony.

16 Why don't we take five minutes at this time? All
17 right? We'll just take a brief five-minute recess so I can
18 pull up the appropriate excerpts and spreadsheets.

19 See you in five minutes.

20 (Recess at 2:24 p.m. until 2:30 p.m.)

21 SPECIAL MASTER VANASKIE: We're back on the record.

22 We're going to go over the designation of testimony
23 for a CVS witness and for a Humana witness.

24 I have received designations of testimony along with
25 objections.

1 I'd like to handle the CVS witness first, if that's
2 all right.

3 And as I understand it, the first objection comes at
4 page 113. Or is it page 112?

5 Go ahead, I'm sorry.

6 MS. GOLDENBERG: So there's two people on the
7 spreadsheet, and we're only designating Cesar Ceden.

8 So from the spreadsheet that I have, I think that
9 they have objections starting at page 25. Is that right,
10 guys?

11 SPECIAL MASTER VANASKIE: So this is Ceden?

12 MS. GOLDENBERG: Yes. So Brais actually wasn't
13 designated; we just didn't take it out because we all knew
14 what we were talking about. I apologize.

15 SPECIAL MASTER VANASKIE: I thought it was Holderman
16 who was the CVS designee.

17 MS. GOLDENBERG: Oh, I'm sorry. It is. Yep. That's
18 why.

19 SPECIAL MASTER VANASKIE: Okay.

20 MS. GOLDENBERG: Okay.

21 SPECIAL MASTER VANASKIE: So I want to go over the
22 designations for Mr. Holderman.

23 (Interruption.)

24 SPECIAL MASTER VANASKIE: And who joined us now?

25 MS. GOLDENBERG: Somebody on a phone.

1 SPECIAL MASTER VANASKIE: Who just joined?

2 MS. LOCKARD: I'm sorry, Judge. It's Victoria
3 Lockard. I have to drive, so I was trying to switch to my
4 phone. I'm sorry for the interruption.

5 SPECIAL MASTER VANASKIE: That's fine.

6 I'd like to cover the areas in dispute with respect
7 to Mr. Holderman's deposition designations.

8 I'm looking at the spreadsheet, and the spreadsheet
9 suggests to me that the first objection should be at page 112,
10 lines 20 to line 24.

11 MR. RAE: Your Honor, I think our first objection is
12 to the designation at page 112, lines 2 to 8, technically 2
13 to 5 that meant 6 to 8, because there's a one-line objection.

14 SPECIAL MASTER VANASKIE: That's page 112, Jacob?

15 MR. RAE: Yes, Your Honor.

16 SPECIAL MASTER VANASKIE: And that's the question:
17 And you also want the drug, CVS does, to be free from defect
18 in design, material and workmanship, correct? You don't want
19 to sell a defective drug, do you?

20 MR. RAE: That's correct, Your Honor.

21 SPECIAL MASTER VANASKIE: What's the objection?

22 MR. RAE: So as a starting point, I think the
23 important thing -- and this is going to frame all of our
24 objections, although there will be some additional specific
25 reasons for individual questions why we're objecting -- is

1 that this issue came up before Judge Bumb at the September 9,
2 2024 hearing. I believe Your Honor was also present or
3 listening in on that hearing.

4 SPECIAL MASTER VANASKIE: You sent me the transcript
5 for that earlier today.

6 MR. RAE: Correct, Your Honor.

7 And defendants' position is, we obviously argued at
8 that hearing, the defense did, that none of this testimony
9 should come in from the retail witnesses. Plaintiffs argued
10 that it should.

11 And the compromise that Judge Bumb ruled was
12 applicable was that plaintiffs are permitted to ask the
13 question, would you knowingly sell adulterated drugs and
14 elicit the answer to that question, which Judge Bumb posited
15 would be no. And I think the transcripts reflect that that's
16 the answer that was given.

17 This question -- and so our objections generally are
18 going to be to the testimony that's designated that goes
19 beyond the scope of what Judge Bumb ruled is permissible.

20 I think that applies to this question. And then, in
21 addition to that -- and we've withdrawn objections to -- to be
22 clear, we've withdrawn objections to the extent the testimony
23 that was designated complies with Judge Bumb's order. And we
24 think there's one question and answer in each of the two
25 transcripts that we're going to be looking at that is close

1 enough to what Judge Bumb ordered was admissible that it
2 follows -- it's within the scope of her order and her ruling.

3 This question we think is well outside of that. It's
4 not asking, would you sell adulterated drugs. It's asking,
5 would you sell defective drugs, would you -- and that's a very
6 different question.

7 It's also one that, frankly, is irrelevant to this
8 litigation. Plaintiffs previously had implied warranty
9 claims, and if they were still asserting their implied
10 warranty claims, we might be having a different conversation
11 here.

12 But this case is not about design defects, it's not
13 about material or workmanship defects. Those issues are not
14 part of the claims that plaintiffs are asserting at the trial.

15 SPECIAL MASTER VANASKIE: All right. Are you arguing
16 this, Marlene?

17 MS. GOLDENBERG: I am. Quick response.

18 So I've got the hearing transcript pulled up as well.
19 And if you look at page 167, she didn't give us, you know, one
20 witness or just a couple sentences. She said -- I'm on
21 lines 12 through 13, again, of page 167. She said: Just call
22 two witnesses. They'll last three minutes. That's it.

23 And that's really all we've designated. So I think
24 what we have here is well within the bounds of what she told
25 us we could do.

1 And the other point that I just wanted to point out
2 on this is that, you know, we've had umpteen discussions about
3 who can say adulteration, what adulteration is. And we've got
4 a witness here who, in his own words, is testifying that they
5 would never sell products that are defective, which is the way
6 in which this witness is capable of testifying. And we're
7 going to get to the adulteration in a bit, because they do
8 actually at these pharmacies have policies about selling
9 adulterated drugs. So they can say that too, but, you know,
10 one way of showing that a drug is adulterated is that it's
11 defective. And so this goes to that claim.

12 And it leads up to the testimony we're about to talk
13 about, which is, you know, how much are these drugs worth.
14 And the testimony that we've chosen for these depositions,
15 which, again, is like super short, is just meant to go to the
16 value of what these drugs are. And that's it. It's pretty
17 simple.

18 SPECIAL MASTER VANASKIE: All right.

19 MR. RAE: Your Honor --

20 MS. KAPKE: CVS --

21 SPECIAL MASTER VANASKIE: You can be heard.

22 And then, Kara, you'll have an opportunity to weigh
23 in as well.

24 MS. KAPKE: Thanks.

25 MR. RAE: I just wanted to very briefly respond to

1 Ms. Goldenberg, to note that the testimony that she quoted
2 from the transcript precedes the testimony that we had
3 directed Your Honor to earlier today and in this hearing.

4 And that our position would be that Judge Bumb was
5 clarifying what she had previously said, that they could
6 ask -- call two witnesses, they could ask them a small limited
7 scope of testimony. And then she goes on to clarify that that
8 testimony is really just a couple of sentences and should be
9 the question, would you knowingly sell adulterated drugs.

10 SPECIAL MASTER VANASKIE: Kara, you wanted to be
11 heard?

12 MS. KAPKE: Thanks, Your Honor.

13 I support the trial defendants' objections, but I'm
14 here basically because we're in the unique position of being a
15 party defendant but not a defendant in this particular trial.

16 SPECIAL MASTER VANASKIE: Right.

17 MS. KAPKE: And I just wanted to make clear on the
18 record that the objections and whatever rulings Your Honor
19 makes with respect to Mr. Holderman are limited to the TPP
20 trial. Obviously, we'd be in a very different situation if
21 CVS were a defendant in the trial where these excerpts are
22 being played. And I wanted to make clear that CVS preserves
23 all its rights, objections regarding playing deposition clips
24 at any trial actually involving CVS as a defendant down the
25 line.

1 So with that stated, I defer to arguments made by the
2 TPP trial defendants.

3 SPECIAL MASTER VANASKIE: All right. And certainly
4 CVS's objections are preserved.

5 MS. KAPKE: Thanks.

6 SPECIAL MASTER VANASKIE: And any ruling I make today
7 concerns only the TPP trial. It doesn't have anything to do
8 with things that will happen in the future.

9 You know, I know this is not, would you sell an
10 adulterated drug and an answer no. It's a little bit beyond
11 that. But it's not horribly beyond it. And I don't think
12 otherwise the question is objectionable.

13 So I will overrule the objection and allow the
14 testimony that's at page 113 of Mr. Holderman's deposition.

15 Are there any other areas of Mr. Holderman's
16 deposition that are at issue?

17 MR. RAE: Your Honor, just to clarify, I think we
18 were currently talking about the testimony at page 112,
19 lines 2 to 8, which relates to a question about defects in
20 design, material and workmanship.

21 SPECIAL MASTER VANASKIE: You are right. Yeah.

22 MS. GOLDENBERG: So that's in.

23 And then I think the only other objection that they
24 had was 113, lines 7 through 11 and then lines 13 through 15.

25 If you want to say that's in too, it'll save us some

1 time.

2 MR. RAE: Your Honor, if I may explain our objection,
3 which is from 113, line 10 to 15. The question and answer --

4 SPECIAL MASTER VANASKIE: Give me a second here,
5 Jacob, just to pull -- so I have the testimony in front of me.

6 I've got so many windows open right now that it has
7 become a challenge.

8 So we're at page 113.

9 MS. GOLDENBERG: Right.

10 SPECIAL MASTER VANASKIE: And what lines are at
11 issue?

12 MR. RAE: Lines 10 to 15.

13 SPECIAL MASTER VANASKIE: Okay. Line 10, by "those
14 products" you mean adulterated products?

15 Object to form.

16 And then the answer is: CVS would not sell -- not
17 knowingly sell, you know, products that are, you know, alleged
18 to have impurities in them.

19 So you're objecting to that?

20 MR. RAE: Yes, Your Honor. And I think that if we go
21 up to the question and answer at line 113, line 2 to 8, this
22 is the testimony that we withdrew our objection to. This is
23 the testimony that we've kind of conceded falls within the
24 scope of what Judge Bumb ruled is permissible. And I think
25 the answer to the question in lines 2 to 8 is clear. The

1 witness was asked if CVS would sell adulterated or misbranded
2 drugs to its customers, and the witness answered that it would
3 not knowingly do so. I think that's exactly the testimony
4 that Judge Bumb envisioned coming in at trial.

5 This next question -- the question itself is
6 unnecessary as a clarifying question here as to what was said
7 in the prior question, but then the answer goes significantly
8 beyond the scope of what Judge Bumb ruled is permissible. And
9 the witness talks about whether or not CVS would sell drugs
10 that are alleged to have impurities in them.

11 And there's a lot of problems with that testimony
12 coming in. The starting point is the witness is referring to
13 drugs -- not even drugs that have impurities in them, which
14 had its own set of problems, but drugs that are alleged to
15 have impurities in them. And that's certainly not a
16 standard that -- I think this witness is misspeaking. That's
17 certainly not a standard that I think CVS would employ for
18 this sort of issue, and it would be prejudicial for the jury
19 to hear this testimony.

20 But even when it comes to impurities themselves, the
21 plaintiffs -- like the -- sorry -- the jury is going to hear
22 from experts in this case and from numerous fact witnesses
23 about the fact that impurities in drug products are normal,
24 that the issue in this case is about nitrosamine impurities,
25 not about impurities at large.

1 And, again, I think the witness is misspeaking here
2 because drug products with impurities that are within
3 specification levels are kind of a normal part of the
4 pharmaceutical manufacturing process and the end products that
5 are sold to consumers. And this testimony is going to be
6 confusing and misleading to the jury because it just doesn't
7 reflect the reality of what CVS does.

8 SPECIAL MASTER VANASKIE: Marlene, why do you need
9 this question at line 10 and the answer, including on line 15?

10 MS. GOLDENBERG: Sure. It completes the answer, Your
11 Honor. And if it was just the second half of this being
12 played, I would understand more where defense counsel is
13 coming from. But because it's -- the answer is given in the
14 context of, you know, these products, all that the witness is
15 expanding on it. And, again, this is their witness's
16 testimony. You know, wherever it goes is where he took it,
17 not, you know, because we baited him into giving some kind of
18 an answer.

19 But, you know, it's given in the context of these
20 valsartan products. You wouldn't want to sell them if they
21 were misbranded. Right? And so the jury is not going to get
22 this answer, like, in isolation. They're going to understand
23 that when he's answering this question about what these
24 products mean, he's saying, no, we don't want to sell products
25 with the alleged impurities in them.

1 And of course everyone by this point in the trial
2 understands that we're talking about valsartan and the NDMA
3 impurities. I don't think anybody is for a second going to
4 think, like, oh, somebody dumped glass in a vial and put it in
5 these pills. No one has been talking about that so far. I
6 can't imagine anyone being confused.

7 SPECIAL MASTER VANASKIE: Well, I think the question
8 and the answer at the top of page 113 are sufficiently clear.
9 CVS doesn't want to sell adulterated or misbranded drugs.

10 This jury is going to hear about adulterated drugs.
11 They're going to know what adulterated drugs are.

12 And the answer is CVS would not knowingly sell those
13 products, clearly referring back to adulterated or misbranded
14 drugs.

15 I don't think you needed to ask what do you mean by
16 those products. I think it's sufficiently clear.

17 So I will sustain the objection and strike lines 10
18 through 15 of page 113.

19 And that concludes Mr. Holderman. Correct?

20 MS. KAPKE: Correct. From my perspective.

21 MR. RAE: That's correct, Your Honor.

22 SPECIAL MASTER VANASKIE: So now we'll go to -- is it
23 Mr. Cedeno?

24 MS. GOLDENBERG: I think we were at where I thought
25 we actually were before. Sorry about that.

1 SPECIAL MASTER VANASKIE: It's all right. I've got
2 to find him again.

3 MS. GOLDENBERG: No excuse for me to be out of place
4 when you've been doing this all day.

5 SPECIAL MASTER VANASKIE: Let me pull it up from the
6 email.

7 And so Ceden, Mr. Ceden is the corporate designee
8 for Humana.

9 And what objection do we have to this one, Jacob?

10 MR. RAE: Are we starting at the question that begins
11 on page 25, line 20?

12 SPECIAL MASTER VANASKIE: We're going to start where
13 your first objection is, so if that's where it is, that's
14 where we'll start.

15 MR. RAE: So this is -- I think this was just kind
16 of -- we are withdrawing our objection to this testimony,
17 because we believe that this question and answer, again, is
18 the one that Judge Bumb said should be coming into trial.

19 SPECIAL MASTER VANASKIE: All right. So the
20 objection is withdrawn.

21 So where is the first -- I just want to rule on what
22 I need to rule on.

23 MR. RAE: I believe the first disputed line of
24 testimony -- the first disputed question begins on line --
25 page 27, line 25, and runs through the answer at page 28,

1 line 9.

2 And then there's another question and answer that
3 follows immediately after that that we're also objecting to at
4 page 28, lines 10 to 13.

5 SPECIAL MASTER VANASKIE: All right. So the question
6 at issue is: And so, again, one of the reasons that Humana
7 recalled its valsartan is because they can't sell drugs that
8 are adulterated, like valsartan that's contaminated with NDMA,
9 right?

10 And the answer is: Yes. Our recall pulls everything
11 we did -- or informed the retail pharmacies of the reasons for
12 the recall, and we immediately stopped selling those products.

13 You're objecting to that then?

14 MR. RAE: That's right, Your Honor.

15 (A discussion off the record.)

16 SPECIAL MASTER VANASKIE: So you're objecting to what
17 I had just read.

18 And why is that?

19 MR. RAE: Yes, Your Honor.

20 So the same objection with respect to this extending
21 beyond the scope of what Judge Bumb ruled is permissible
22 testimony, but there's a specific problem with this testimony
23 that relates to the implication -- the question asks that one
24 of the reasons that Humana recalled its valsartan products is
25 because they can't sell drugs that are adulterated like

1 valsartan that's contaminated with NDMA. Right?

2 And implicit in that question, layered into that
3 question is the view of plaintiffs in this case, something
4 that plaintiffs are arguing to the jury, that Judge Bumb in an
5 order earlier today confirmed is a question for the jury to
6 decide as to whether or not the at-issue products in this case
7 are adulterated or not.

8 And so this question, because it's framed that way,
9 calls for a legal conclusion. It in fact goes beyond calling
10 for a legal conclusion and just plants a legal conclusion into
11 the question. And it's therefore improper and shouldn't be
12 coming into the case.

13 SPECIAL MASTER VANASKIE: Marlene?

14 MS. GOLDENBERG: There are objections to this
15 question, but neither of them are calling for a legal
16 conclusion, so that one's new.

17 But I will say too, this doesn't imply anything. All
18 it does is it posits, you know, are you allowed to sell this
19 product and is this an example of a type of product you're not
20 allowed to sell.

21 It doesn't anywhere say, you know, that the drugs are
22 contaminated with the NDMA. And if there's something that
23 Judge Bumb ruled is a jury question, well, gosh, I sure hope
24 we're allowed to present testimony that allows them to make
25 that choice. Otherwise, they're making that choice in a

1 vacuum. So I think this is squarely within the bounds of what
2 was contemplated.

3 SPECIAL MASTER VANASKIE: Yes. I think the problem
4 with the question is that it includes "like valsartan that's
5 contaminated with NDMA."

6 So it's telling the jury valsartan is adulterated.
7 And I think you can say that, but ultimately the jury has to
8 conclude that.

9 So I will sustain the objection and strike that
10 testimony, that question and answer on page 27, lines 25 to
11 page 28, line 3 and then page 28, lines 6 to 9.

12 MS. GOLDENBERG: Just for the sake of the record,
13 Your Honor, I just want to point out that the question doesn't
14 actually say that valsartan is adulterated. It just says that
15 CVS or Humana can't sell drugs that are adulterated, and then
16 it gives as a modifier "like valsartan that's contaminated
17 with NDMA." And there's no dispute that valsartan was
18 contaminated with the NDMA. Right? Like, that's a fact
19 accepted by all the parties.

20 And so I understand your ruling, but just wanted to
21 make sure that was there.

22 SPECIAL MASTER VANASKIE: Yes. Okay. Very well.
23 What else do we have with respect to Mr. Cedeno?

24 MR. RAE: The next objection is at -- it's the very
25 next question, which is a follow-up to a question and answer

1 we were just discussing.

2 Our objections are fairly similar. The question
3 asks: Because you couldn't sell a product that had unsafe
4 levels of nitrosamines, right?

5 That, again, goes beyond the scope of what Judge Bumb
6 ruled should come in and asks this witness to -- without
7 foundation, posits that these products have unsafe levels of
8 nitrosamines and calls for a legal conclusion as to whether or
9 not the at-issue products here had unsafe levels of
10 nitrosamines.

11 Those are all issues of facts in this case. They're
12 going to be coming to the jury through kind of witnesses that
13 are appropriately positioned as fact witnesses or experts to
14 comment on safety issues with these products. It's not an
15 issue for a pharmacy defendant to be opining on.

16 SPECIAL MASTER VANASKIE: Marlene?

17 MS. GOLDENBERG: So, again, this is a 30(b)(6)
18 witness who was designated precisely for the purpose of
19 answering questions just like this, like, what can a pharmacy
20 sell and what won't they sell. And that, as a private
21 company, is their choice.

22 And there's no legal conclusion in here. I mean, the
23 word "unsafe" is not a legal term. Right? It's just would
24 you sell products with unsafe levels of nitrosamines.

25 And, you know, the witness understood the question,

1 didn't ask for any clarifying, you know, questions following
2 up on it. And he said in this situation, in this recall, yes.
3 Which means he understood it, he qualified it, he answered it
4 with a very clear absolutely. And so I don't think there's
5 anything legal about this.

6 SPECIAL MASTER VANASKIE: Yes, I agree. I think this
7 question, unlike the other one, is appropriate. It's not
8 using the word "adulterated," and I don't see anything
9 objectionable about it.

10 I'll therefore overrule the objection, and 10 to 13
11 on page 28 stays in.

12 Are there any other objections?

13 MR. RAE: Yes.

14 MS. GOLDENBERG: We're up to page 30.

15 SPECIAL MASTER VANASKIE: Go ahead, Jacob.

16 MR. RAE: Our next objection is to testimony that
17 begins on page 30, line 25 and runs through -- the first
18 answer runs through page 31, line 3. And then there's several
19 other questions and answers on page 31.

20 So the question -- the first question here that's
21 being asked is: For every pill that Humana would sell,
22 whatever that monetary value is, is what they would make off
23 of the pill, right?

24 And the answer was: Sometimes you lose money, but,
25 yes.

1 And to start with, I think this is dramatically
2 afield from the scope of questioning that Judge Bumb ruled
3 could come in with respect to these pharmacy witnesses. Judge
4 Bumb was very clear the scope of testimony that can come into
5 this trial from the pharmacy witnesses needs to be related to,
6 in Judge Bumb's words, just this question about whether or not
7 they would sell adulterated products, but certainly doesn't
8 extend beyond questions about the types of products that these
9 pharmacy retailer, like, parties would be willing to sell into
10 what they view as having value to them.

11 And there's a number of problems with getting into
12 that line of questioning. It kind of lacks foundation and is
13 outside the scope of the 30(b)(6) deposition, but it's also --
14 and I think part of the concern that animated Judge Bumb's
15 limitation here is that this would be incredibly confusing as
16 a line of questioning, because, again, one of the central
17 issues in this case that the jury is going to be called upon
18 to decide is whether or not the products at issue in this
19 litigation have value to the TPPs who are the plaintiffs in
20 this litigation. And this is asking Humana whether or not
21 these products have value from Humana's perspective as a
22 pharmacy and as a retailer.

23 And that's a very different topic. And to have kind
24 of just a few lines of testimony come into the trial about
25 that issue is going to be confusing, and it's going to

1 potentially create a need for defendants to kind of -- for
2 there to be a digression at trial about distinguishing between
3 value to pharmacists and retailers and value to third-party
4 purchasers that there's just no reason for any of us to be
5 getting into.

6 SPECIAL MASTER VANASKIE: Marlene?

7 MS. GOLDENBERG: I think it's pretending there's a
8 sideshow when there isn't one. I mean, if a pharmacy can't
9 sell a pill, then of course a third-party payor isn't going to
10 pay for it. They're one and the same. There's no need for
11 anyone to explain that. I think it's pretty intuitive to
12 understand that if a pharmacy isn't dispensing something,
13 then, like, that value -- if that value is zero, the value to
14 the TPP is obviously zero as well.

15 But we need to look at this question in the context
16 of really just this whole page on -- well, you know, the very
17 end of 30 to page 31, because what this line of questioning
18 culminates in is, if you can't sell something, then it's not
19 worth anything, right? And there's no legal conclusion or
20 anything about that. That's just layman's terms, contracts
21 101, which is something is worth exactly what you're going to
22 pay for it.

23 And the defendants are going to put on their case
24 about how they think these pills still have some value.

25 We have their seller testifying that they don't think

1 it has any value. And that goes directly to one of the
2 biggest defenses in this case. And this is, you know, someone
3 they sold their pills to.

4 So we think that this is pretty important, that
5 someone that these defendants are selling their pills to is
6 saying, no, no, we agree. Like, if we had known these things
7 were contaminated, we wouldn't have sold this stuff. That's a
8 big deal.

9 SPECIAL MASTER VANASKIE: Yes. I'll overrule this
10 objection and allow the testimony -- the questions and the
11 testimony on page 31 to be presented to the jury.

12 MR. RAE: Your Honor, if I may briefly kind of speak
13 again on this issue, if you would permit.

14 SPECIAL MASTER VANASKIE: Yes. Certainly. Go ahead.

15 MR. RAE: I think that the Court just this morning
16 issued an order that I think is directly on point for why this
17 testimony should not come in. And this was -- it was a
18 rescheduling order primarily, but in that rescheduling order,
19 which is at ECF Number 2881, Judge Bumb remarked that the
20 determination of adulteration -- namely, whether the
21 Defendants' VCDs were adulterated and, if so, for what
22 period -- is solely for the jury to be made. To be clear, no
23 testimony will be permitted suggesting that the mere fact of
24 the FDA's finding of adulteration and recall in 2018 is
25 sufficient to establish adulteration retroactively to 2012.

1 And then she goes on to comment that Dr. Conti's
2 testimony on these issues will not be permitted.

3 This is the exact argument that plaintiffs are trying
4 to present through the designated testimony here. They're
5 basically trying to establish that because these pills were at
6 a later point in time determined to be adulterated, that they
7 couldn't have been sold earlier and therefore were worthless.
8 And that's testimony that Judge Bumb has been clear is not to
9 come into trial.

10 And it shouldn't be any different because this is a
11 fact -- a non-party fact witness giving this testimony than it
12 was when an expert was trying to give this testimony.

13 SPECIAL MASTER VANASKIE: Marlene?

14 MS. GOLDENBERG: I don't think it does that. You
15 know, all these fact witnesses are being asked is, would you,
16 as a third party who is in the, you know, regular business of
17 selling drugs, valuing them when you buy them and valuing them
18 when you sell them, like, this is what they do for a living,
19 would you sell this product if you knew this.

20 And it's a very straightforward answer. There's no
21 expert testimony about adulteration in here. It's just would
22 you, as a business that does this every single day in and out,
23 do this if you had known this.

24 I don't think we're into what Judge Bumb talked about
25 at all.

1 SPECIAL MASTER VANASKIE: Well, it is a perplexing
2 question because we're looking at they were sold. They were
3 sold for a number of years. And to now say that they were
4 worthless when people paid money for them and third-party
5 payors paid money for them not knowing that they were
6 adulterated, it is going to be a question that perplexes the
7 Court, I fear.

8 Having said all that, I still think this is
9 appropriate testimony to present to the jury and will overrule
10 the objection and stand by my ruling.

11 I think somebody is going to have to get up and say,
12 you know, we never would have sold them or they would have had
13 no value to us. It's unfortunate, but in this breach of
14 warranty, at least as far as the breach of warranty claim is
15 concerned, if you buy something that turns out to be
16 worthless, well, what's your measure of damages. And that's
17 what you're going to have to wrestle with.

18 It turns out to be worthless because it was
19 contaminated now. They didn't know it was contaminated. And
20 what do you do then?

21 It had therapeutic properties, I am sure.

22 Do you find a way to value the therapeutic
23 properties? Can you? I really don't know.

24 The plaintiffs will have a theory and defense will
25 have a theory, and the jury will ultimately be called upon to

1 decide which theory is more persuasive.

2 I think -- but -- that's where we stand, but I think
3 the jury should know this testimony, and so I will overrule
4 the objection.

5 But well argued.

6 Anything else on Mr. Cedenno?

7 MS. GOLDENBERG: No. I think we're done, Your Honor.

8 MR. RAE: I think so too, Your Honor.

9 I would just highlight that I think a particularly
10 troublesome question in this line of questioning, although we
11 object to all of it from the defense perspective, is the
12 question at 31, line 4 to 9, where the question is asked: But
13 that pill isn't worth anything if it's contaminated with
14 nitrosamines, right?

15 And the answer is: So it would not benefit Humana or
16 the patient to dispense that pill.

17 And, again, I think this is clearly invading the
18 province that the Court has held is for the jury to decide in
19 this case, that the Court in its order just this morning was
20 clear that this theory of kind of a full refund based on the
21 products being economically worthless needs to be based on
22 evidence of the actual value of these products, not based
23 solely on this theory that the mere presence of nitrosamines
24 renders the products worthless as kind of an abstract or legal
25 matter.

1 SPECIAL MASTER VANASKIE: I think it will be a matter
2 of proof. And I do think that the plaintiffs are entitled to
3 present their theory that the -- because of the contamination,
4 the products had no value.

5 The warranty that the products were FDA compliant was
6 breached, and then have to argue over what's the measure of
7 damages.

8 I understand your argument, Jacob, and it's well
9 presented, but my ruling stands.

10 MR. RAE: I understand.

11 SPECIAL MASTER VANASKIE: And, you know, this gets
12 played, and you can always ask the judge to strike the
13 testimony or seek reconsideration from Judge Bumb. But I
14 don't think this goes too far. All right?

15 Anything else then today?

16 MS. GOLDENBERG: Last question --

17 MR. STANOCH: Judge, David Stanoch -- I was just
18 going to -- if we're done with retailers, I was just going to
19 ask about logistics with Teva witness Binsol and if we should
20 get a time on for Monday or Tuesday about that. That's all.

21 SPECIAL MASTER VANASKIE: All right.

22 MS. LOCKARD: I'm on, Your Honor. It's Victoria.
23 So I have a conflict on Monday.

24 I could do it -- I believe we have -- well, I guess
25 Judge Bumb rescheduled our Tuesday conference, so I'm free on

1 Tuesday.

2 SPECIAL MASTER VANASKIE: Let me look at my calendar.

3 I could do it Tuesday. So why don't we set aside --
4 and, Larry, if you could set this up for Tuesday at 10:00 a.m.
5 again -- for Mr. Binsol?

6 MS. LOCKARD: Mr. Binsol, right, Tony Binsol.

7 SPECIAL MASTER VANASKIE: Anything else in terms
8 of --

9 MS. LOCKARD: I did have one other thing, Your Honor,
10 just quickly.

11 SPECIAL MASTER VANASKIE: Go ahead.

12 MS. LOCKARD: I believe that we have a pretrial Zoom
13 hearing set with Your Honor upcoming between now and trial.
14 And that I think is to discuss primarily the pretrial order.

15 SPECIAL MASTER VANASKIE: Correct.

16 MS. LOCKARD: The parties are working together to try
17 to get -- we're trying to schedule a meet and confer, frankly,
18 for early next week so that we can figure out what needs to be
19 done.

20 But I don't know if you've given any thought to what
21 the order of the day needs to be, if there's anything in
22 particular we need to know going into that, which should be
23 helpful.

24 The pretrial order, I don't know if you've looked at
25 it, but it is a -- it is not a light read.

1 SPECIAL MASTER VANASKIE: It's about 250 pages.

2 Right?

3 MS. LOCKARD: I think that's about right. I stopped
4 counting.

5 So just so we could make the most of the time and be
6 prepared, if you had any thoughts or if you want to share with
7 us next week, I just thought I would ask.

8 SPECIAL MASTER VANASKIE: I really appreciate you
9 raising that issue now.

10 Let's plan on talking about that next Tuesday. The
11 pretrial is scheduled for Friday at -- I have it at 10:30 a.m.
12 on Friday the 11th. And I'll give you more guidance then.

13 You know, my intention is to get the final pretrial
14 order finalized. And that's why I asked if you could send me
15 your competing versions or send me one version in redline
16 format, I can tell from the redlines who is making the
17 proposed changes and who's objecting to aspects of it. And
18 right now my intention was to go over the final pretrial
19 order.

20 I'm not sure what else needs to be reviewed, then, at
21 the final pretrial conference. And why don't you give that
22 some thought and be prepared to address it on Tuesday, October
23 8th.

24 MS. LOCKARD: Absolutely. We'll be prepared.

25 SPECIAL MASTER VANASKIE: All right. David or

1 Marlene, anything else on this?

2 MR. STANOCH: The only other scheduling issue I think
3 I have, Judge, is that wholesaler motion. And I'm only
4 raising it because there's so much going on obviously for
5 trial, but there may be technically a deadline because they
6 filed it on the docket.

7 We can --

8 SPECIAL MASTER VANASKIE: That's for the other
9 sartans, though. It's not involving this.

10 MR. STANOCH: 100 percent, Judge, but --

11 SPECIAL MASTER VANASKIE: I wanted to defer that
12 until after we got through this.

13 MR. STANOCH: I just don't want to waive my response
14 time under the local rules of the district. That's all.
15 That's my only issue.

16 SPECIAL MASTER VANASKIE: Well, submit a letter
17 asking for a date certain for your response, and we'll issue
18 an order.

19 MR. STANOCH: Yes, sir.

20 SPECIAL MASTER VANASKIE: All right? So you're not
21 worried about it, you know, so you get the comfort of having
22 an order in place that says my response is due on this such
23 and such a date. All right?

24 MR. STANOCH: Yes, sir. Thank you, Judge.

25 MS. SMITH: Excuse me, Judge, it's Loretta.

1 SPECIAL MASTER VANASKIE: Yes, Loretta.

2 MS. SMITH: Hi. You mentioned just now an
3 October 8th hearing. I don't have that on the calendar.

4 SPECIAL MASTER VANASKIE: No. We're just adding it
5 now.

6 MS. SMITH: Okay. Sorry.

7 SPECIAL MASTER VANASKIE: We're adding it now. This
8 is because the Binsol designations were just recently
9 exchanged, and I do have oral argument on Monday. And this is
10 to deal with the testimony or proposed testimony of Maggie
11 Kong and Mr. Lin.

12 But we'll take up the Binsol matter on Tuesday. All
13 right?

14 MS. SMITH: Is there a time, Judge, that you stated?
15 I missed it. I'm sorry.

16 SPECIAL MASTER VANASKIE: That's all right.
17 10:00 a.m. on Tuesday, October 8th. And Larry, if Larry is
18 still on, we can make the arrangement for the Teams session
19 then.

20 And if you could do a text order, Loretta, that would
21 be great.

22 Any questions?

23 (A discussion off the record occurred.)

24 SPECIAL MASTER VANASKIE: Anything else for today?

25 (No response.)

1 SPECIAL MASTER VANASKIE: Well, try to enjoy the
2 weekend. Thank you all.

3 RESPONSE: Thank you, Judge.

4 (Proceedings concluded at 3:11 p.m.)

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6 **FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE**

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8 I certify that the foregoing is a correct transcript
9 from the record of proceedings in the above-entitled matter.

10

11 /S/ Ann Marie Mitchell 4th day of October, 2024
12 CCR-RDR-RMR-CRR
Court Reporter/Transcriber

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